

**PB 14 of 2024**

**National Health Legislation Amendment (Maximum Dispensed Quantities) Instrument 2024**

*National Health Act 1953*

I, NIKOLAI TSYGANOV, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 28 February 2024

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

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National Health (Listing of Pharmaceutical Benefits) Instrument 2012. 2

1 Name

1. This instrument is the *National Health* *Legislation Amendment (**Maximum Dispensed Quantities) Instrument 2024*.
2. This instrument may also be cited as PB 14 of 2024.

2 Commencement

1. Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information | | |
| --- | --- | --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. *The whole of this instrument* | *1 March 2024* | *1 March 2024* |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

1. Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Maximum dispensed quantities

*National Health (Listing of Pharmaceutical Benefits) Instrument 2012*

1. **Schedule 1, Part 1, entry for Acarbose**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Acarbose | Tablet 50 mg | Oral | a | Acarbose Mylan | AF | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Acarbose Viatris | AL | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | GLYBOSAY | RW | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Acarbose Mylan | AF | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Acarbose Viatris | AL | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | GLYBOSAY | RW | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  | Tablet 100 mg | Oral | a | Acarbose Viatris | AL | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | GLYBOSAY | RW | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Acarbose Viatris | AL | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | GLYBOSAY | RW | MP NP |  | P14238 | 180 | 5 | 90 |  |  |

1. **Schedule 1, Part 1, entry for Alendronic acid with colecalciferol**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Alendronic acid with colecalciferol | Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol | Oral |  | Fosamax Plus | MQ | MP NP | C6307 C6315 C6320 C15011 C15024 C15035 | P6307 P6315 P6320 | 4 | 5 | 4 |  |  |
|  |  |  |  |  |  | MP NP | C6307 C6315 C6320 C15011 C15024 C15035 | P15011 P15024 P15035 | 8 | 5 | 4 |  |  |
|  | Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol | Oral |  | Fosamax Plus 70 mg/140 mcg | MQ | MP NP | C6306 C6319 C6325 C14898 C14993 C15032 | P6306 P6319 P6325 | 4 | 5 | 4 |  |  |
|  |  |  |  |  |  | MP NP | C6306 C6319 C6325 C14898 C14993 C15032 | P14898 P14993 P15032 | 8 | 5 | 4 |  |  |

1. **Schedule 1, Part 1, entry for Alogliptin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Alogliptin | Tablet 6.25 mg (as benzoate) | Oral |  | Nesina | TK | MP NP | C4349 C14862 | P4349 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4349 C14862 | P14862 | 56 | 5 | 28 |  |  |
|  | Tablet 12.5 mg (as benzoate) | Oral |  | Nesina | TK | MP NP | C4349 C14862 | P4349 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4349 C14862 | P14862 | 56 | 5 | 28 |  |  |
|  | Tablet 25 mg (as benzoate) | Oral |  | Nesina | TK | MP NP | C4349 C14862 | P4349 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4349 C14862 | P14862 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Alogliptin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride | Oral |  | Nesina Met 12.5/1000 | TK | MP NP | C4423 C4427 C14876 | P4423 P4427 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C4423 C4427 C14876 | P14876 | 112 | 5 | 56 |  |  |
|  | Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride | Oral |  | Nesina Met 12.5/500 | TK | MP NP | C4423 C4427 C14876 | P4423 P4427 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C4423 C4427 C14876 | P14876 | 112 | 5 | 56 |  |  |
|  | Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride | Oral |  | Nesina Met 12.5/850 | TK | MP NP | C4423 C4427 C14876 | P4423 P4427 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C4423 C4427 C14876 | P14876 | 112 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Amlodipine with atorvastatin in the form Tablet 10 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 10 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium) | Oral | a | Cadivast 10/80 | AF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Caduet 10/80 | AS | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Cadivast 10/80 | AF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Caduet 10/80 | AS | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Anastrozole**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Anastrozole | Tablet 1 mg | Oral | a | Anastrozole GH | GQ | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Anastrozole Sandoz | SZ | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | APO-Anastrozole | TX | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Arianna 1 | AF | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Arimidex | AP | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Anastrozole GH | GQ | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Anastrozole Sandoz | SZ | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | APO-Anastrozole | TX | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Arianna 1 | AF | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Arimidex | AP | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Bromocriptine**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bromocriptine | Tablet 2.5 mg (as mesilate) | Oral |  | Parlodel | SZ | MP | C5172 C6706 C6707 C6717 C6718 C6719 C6787 C14914 C14981 C15017 C15028 C15043 C15044 | P5172 | 30 | 0 | 30 |  |  |
|  |  |  |  |  |  | NP | C5172 |  | 30 | 0 | 30 |  |  |
|  |  |  |  |  |  | MP | C5172 C6706 C6707 C6717 C6718 C6719 C6787 C14914 C14981 C15017 C15028 C15043 C15044 | P6706 P6707 P6717 P6718 P6719 P6787 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C5172 C6706 C6707 C6717 C6718 C6719 C6787 C14914 C14981 C15017 C15028 C15043 C15044 | P14914 P14981 P15017 P15028 P15043 P15044 | 120 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Cabergoline in the form Tablet 500 micrograms**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cabergoline | Tablet 500 micrograms | Oral |  | Dostinex | PF | MP | C5136 C5137 C5172 C5357 C5398 C14918 C14959 C14983 C15005 | P5172 | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | NP | C5172 |  | 2 | 0 | 2 |  |  |
|  |  |  |  |  |  | MP | C5136 C5137 C5172 C5357 C5398 C14918 C14959 C14983 C15005 | P5136 P5137 P5357 P5398 | 8 | 5 | 8 |  |  |
|  |  |  |  |  |  | MP | C5136 C5137 C5172 C5357 C5398 C14918 C14959 C14983 C15005 | P14918 P14959 P14983 P15005 | 16 | 5 | 8 |  |  |

1. **Schedule 1, Part 1, entry for Carbamazepine in the form Oral suspension 100 mg per 5 mL, 300 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Carbamazepine | Oral suspension 100 mg per 5 mL, 300 mL | Oral |  | Tegretol Liquid | NV | PDP |  |  | 1 | 0 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Carbamazepine in the form Tablet 200 mg (controlled release)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 200 mg (controlled release) | Oral |  | Tegretol CR 200 | NV | PDP |  |  | 200 | 0 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |

1. **Schedule 1, Part 1, entry for Carbamazepine in the form Tablet 400 mg (controlled release)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 400 mg (controlled release) | Oral |  | Tegretol CR 400 | NV | PDP |  |  | 200 | 0 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |

1. **Schedule 1, Part 1, entry for Carbimazole**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Carbimazole | Tablet 5 mg | Oral | a | Neo-Mercazole | GH | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | THIRAZOL | NB | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | WP Carbimazole | TN | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Neo-Mercazole | GH | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | THIRAZOL | NB | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | WP Carbimazole | TN | MP NP |  | P14238 | 400 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 10 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Ciclosporin | Capsule 10 mg | Oral |  | Neoral 10 | NV | MP |  |  | 120 | 3 | 60 |  |  |
|  |  |  |  |  |  | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 60 |  | C(100) |
|  |  |  |  |  |  | MP |  | P14238 | 240 | 3 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 25 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule 25 mg | Oral | a | APO-Ciclosporin | TX | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | Neoral 25 | NV | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | APO-Ciclosporin | TX | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | Neoral 25 | NV | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | APO-Ciclosporin | TX | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |
|  |  |  | a | Neoral 25 | NV | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |

1. **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 50 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule 50 mg | Oral | a | APO-Ciclosporin | TX | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | Neoral 50 | NV | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | APO-Ciclosporin | TX | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | Neoral 50 | NV | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | APO-Ciclosporin | TX | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |
|  |  |  | a | Neoral 50 | NV | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |

1. **Schedule 1, Part 1, entry for Ciclosporin in the form Capsule 100 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule 100 mg | Oral | a | APO-Ciclosporin | TX | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | Neoral 100 | NV | MP |  |  | 60 | 3 | 30 |  |  |
|  |  |  | a | APO-Ciclosporin | TX | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | Neoral 100 | NV | MP |  | P14238 | 120 | 3 | 30 |  |  |
|  |  |  | a | APO-Ciclosporin | TX | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |
|  |  |  | a | Cyclosporin Sandoz | SZ | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |
|  |  |  | a | Neoral 100 | NV | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 120 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 30 |  | C(100) |

1. **Schedule 1, Part 1, entry for Ciclosporin in the form Oral liquid 100 mg per mL, 50 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Oral liquid 100 mg per mL, 50 mL | Oral |  | Neoral | NV | MP |  |  | 2 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 4 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP |  | P6631 P6638 P6643 P6660 P9694 P9695 P9742 P9764 P13122 P13168 | 4 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 5 CN6631 CN6638 CN6643 CN6660 CN9694 CN9695 CN9742 CN9764 CN13122 CN13168 | 1 |  | C(100) |

1. **Schedule 1, Part 1, entry for Cortisone**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cortisone | Tablet containing cortisone acetate 5 mg | Oral |  | Cortate | AS | MP NP |  |  | 50 | 4 | 50 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 100 | 4 | 50 |  |  |
|  | Tablet containing cortisone acetate 25 mg | Oral |  | Cortate | AS | MP NP |  |  | 60 | 4 | 60 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 120 | 4 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Cyproterone**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Cyproterone | Tablet containing cyproterone acetate 50 mg | Oral | a | ANTERONE 50 | RW | MP |  | P5532 | 20 CN5532 | 5 CN5532 | 20 |  |  |
|  |  |  | a | Cyproterone Sandoz | HX | MP |  | P5532 | 20 CN5532 | 5 CN5532 | 20 |  |  |
|  |  |  | a | Pharmacor Cyproterone 50 | CR | MP |  | P5532 | 20 CN5532 | 5 CN5532 | 20 |  |  |
|  |  |  | a | ANTERONE 50 | RW | MP |  | P14868 | 40 CN14868 | 5 CN14868 | 20 |  |  |
|  |  |  | a | Cyproterone Sandoz | HX | MP |  | P14868 | 40 CN14868 | 5 CN14868 | 20 |  |  |
|  |  |  | a | Pharmacor Cyproterone 50 | CR | MP |  | P14868 | 40 CN14868 | 5 CN14868 | 20 |  |  |
|  |  |  | a | Androcur | BN | MP |  |  | 100 | 5 | 50 |  |  |
|  |  |  | a | ANTERONE 50 | RW | MP |  |  | 100 | 5 | 50 |  |  |
|  |  |  | a | Cyproterone Sandoz | HX | MP |  |  | 100 | 5 | 50 |  |  |
|  |  |  | a | Pharmacor Cyproterone 50 | CR | MP |  |  | 100 | 5 | 50 |  |  |
|  |  |  | a | Androcur | BN | MP |  | P14238 | 200 | 5 | 50 |  |  |
|  |  |  | a | ANTERONE 50 | RW | MP |  | P14238 | 200 | 5 | 50 |  |  |
|  |  |  | a | Cyproterone Sandoz | HX | MP |  | P14238 | 200 | 5 | 50 |  |  |
|  |  |  | a | Pharmacor Cyproterone 50 | CR | MP |  | P14238 | 200 | 5 | 50 |  |  |
|  | Tablet containing cyproterone acetate 100 mg | Oral | a | Androcur-100 | BN | MP |  |  | 50 | 5 | 50 |  |  |
|  |  |  | a | ANTERONE 100 | RW | MP |  |  | 50 | 5 | 50 |  |  |
|  |  |  | a | Cyproterone Sandoz | HX | MP |  |  | 50 | 5 | 50 |  |  |
|  |  |  | a | Pharmacor Cyproterone 100 | CR | MP |  |  | 50 | 5 | 50 |  |  |
|  |  |  | a | Androcur-100 | BN | MP |  | P14238 | 100 | 5 | 50 |  |  |
|  |  |  | a | ANTERONE 100 | RW | MP |  | P14238 | 100 | 5 | 50 |  |  |
|  |  |  | a | Cyproterone Sandoz | HX | MP |  | P14238 | 100 | 5 | 50 |  |  |
|  |  |  | a | Pharmacor Cyproterone 100 | CR | MP |  | P14238 | 100 | 5 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Dapagliflozin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dapagliflozin | Tablet 10 mg (as propanediol monohydrate) | Oral |  | Forxiga | AP | MP | C4991 C5629 C7495 C7506 C7528 C12477 C13230 C14859 C14905 C14949 C14974 C14976 | P4991 P5629 P7495 P7506 P7528 P12477 P13230 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C4991 C5629 C7495 C7506 C12477 C13230 C14859 C14905 C14949 C14974 C14976 | P4991 P5629 P7495 P7506 P12477 P13230 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C4991 C5629 C7495 C7506 C7528 C12477 C13230 C14859 C14905 C14949 C14974 C14976 | P14859 P14905 P14949 P14974 P14976 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C4991 C5629 C7495 C7506 C12477 C13230 C14859 C14905 C14949 C14974 C14976 | P14859 P14905 P14949 P14974 P14976 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Dapagliflozin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dapagliflozin with metformin | Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | Oral |  | Xigduo XR 5/1000 | AP | MP | C5631 C5657 C5739 C5798 C7492 C7498 C14878 C14881 C14924 C14987 | P5631 P5657 P5739 P5798 P7492 P7498 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C5631 C5657 C5739 C5798 C7492 C14878 C14881 C14924 C14987 | P5631 P5657 P5739 P5798 P7492 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP | C5631 C5657 C5739 C5798 C7492 C7498 C14878 C14881 C14924 C14987 | P14878 P14881 P14924 P14987 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C5631 C5657 C5739 C5798 C7492 C14878 C14881 C14924 C14987 | P14878 P14881 P14924 P14987 | 112 | 5 | 56 |  |  |
|  | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride | Oral |  | Xigduo XR 10/500 | AP | MP | C5631 C5657 C5739 C5798 C7492 C7498 C14878 C14881 C14924 C14987 | P5631 P5657 P5739 P5798 P7492 P7498 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C5631 C5657 C5739 C5798 C7492 C14878 C14881 C14924 C14987 | P5631 P5657 P5739 P5798 P7492 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C5631 C5657 C5739 C5798 C7492 C7498 C14878 C14881 C14924 C14987 | P14878 P14881 P14924 P14987 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C5631 C5657 C5739 C5798 C7492 C14878 C14881 C14924 C14987 | P14878 P14881 P14924 P14987 | 56 | 5 | 28 |  |  |
|  | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | Oral |  | Xigduo XR 10/1000 | AP | MP | C5631 C5657 C5739 C5798 C7492 C7498 C14878 C14881 C14924 C14987 | P5631 P5657 P5739 P5798 P7492 P7498 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C5631 C5657 C5739 C5798 C7492 C14878 C14881 C14924 C14987 | P5631 P5657 P5739 P5798 P7492 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C5631 C5657 C5739 C5798 C7492 C7498 C14878 C14881 C14924 C14987 | P14878 P14881 P14924 P14987 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C5631 C5657 C5739 C5798 C7492 C14878 C14881 C14924 C14987 | P14878 P14881 P14924 P14987 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Desmopressin in the form Tablet containing desmopressin acetate 200 micrograms**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing desmopressin acetate 200 micrograms | Oral |  | Minirin | FP | MP | C5266 C5295 C5413 C14842 C14972 C15012 | P5295 P5413 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5295 C5413 C14842 C14972 | P5295 P5413 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C5266 C5295 C5413 C14842 C14972 C15012 | P14842 P14972 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5295 C5413 C14842 C14972 | P14842 P14972 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C5266 C5295 C5413 C14842 C14972 C15012 | P5266 | 90 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C5266 C5295 C5413 C14842 C14972 C15012 | P15012 | 180 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Desmopressin in the form Wafer 120 micrograms (as acetate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Wafer 120 micrograms (as acetate) | Sublingual |  | Minirin Melt | FP | MP NP | C5226 C5412 C14842 C14972 | P5226 P5412 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP NP | C5226 C5412 C14842 C14972 | P14842 P14972 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Desmopressin in the form Wafer 240 micrograms (as acetate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Wafer 240 micrograms (as acetate) | Sublingual |  | Minirin Melt | FP | MP NP | C5226 C5412 C14945 C15025 | P5226 P5412 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP NP | C5226 C5412 C14945 C15025 | P14945 P15025 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Dexamethasone in the form Tablet 500 micrograms**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 500 micrograms | Oral |  | Dexmethsone | AS | MP NP |  |  | 30 | 4 | 30 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 60 | 4 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Dutasteride**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dutasteride | Capsule 500 micrograms | Oral | a | APO-Dutasteride | TX | MP NP | C6202 C15018 | P6202 | 30 | 5 | 30 |  |  |
|  |  |  | a | Avodart | GK | MP NP | C6202 C15018 | P6202 | 30 | 5 | 30 |  |  |
|  |  |  | a | APO-Dutasteride | TX | MP NP | C6202 C15018 | P15018 | 60 | 5 | 30 |  |  |
|  |  |  | a | Avodart | GK | MP NP | C6202 C15018 | P15018 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Dutasteride with tamsulosin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dutasteride with tamsulosin | Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms | Oral | a | Doubluts | GC | MP NP | C6189 C15004 | P6189 | 30 | 5 | 30 |  |  |
|  |  |  | a | Duodart 500ug/400ug | GK | MP NP | C6189 C15004 | P6189 | 30 | 5 | 30 |  |  |
|  |  |  | a | Doubluts | GC | MP NP | C6189 C15004 | P15004 | 60 | 5 | 30 |  |  |
|  |  |  | a | Duodart 500ug/400ug | GK | MP NP | C6189 C15004 | P15004 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Empagliflozin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Empagliflozin | Tablet 10 mg | Oral |  | Jardiance | BY | MP | C4991 C5629 C7495 C7506 C7528 C12477 C14471 C14859 C14905 C14949 C14974 C14976 | P4991 P5629 P7495 P7506 P7528 P12477 P14471 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C4991 C5629 C7495 C7506 C12477 C14471 C14859 C14905 C14949 C14974 C14976 | P4991 P5629 P7495 P7506 P12477 P14471 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C4991 C5629 C7495 C7506 C7528 C12477 C14471 C14859 C14905 C14949 C14974 C14976 | P14859 P14905 P14949 P14974 P14976 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C4991 C5629 C7495 C7506 C12477 C14471 C14859 C14905 C14949 C14974 C14976 | P14859 P14905 P14949 P14974 P14976 | 60 | 5 | 30 |  |  |
|  | Tablet 25 mg | Oral |  | Jardiance | BY | MP | C4991 C5629 C7495 C7506 C7528 C14859 C14905 C14949 C14974 | P4991 P5629 P7495 P7506 P7528 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C4991 C5629 C7495 C7506 C14859 C14905 C14949 C14974 | P4991 P5629 P7495 P7506 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C4991 C5629 C7495 C7506 C7528 C14859 C14905 C14949 C14974 | P14859 P14905 P14949 P14974 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C4991 C5629 C7495 C7506 C14859 C14905 C14949 C14974 | P14859 P14905 P14949 P14974 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Empagliflozin with linagliptin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Empagliflozin with linagliptin | Tablet containing 10 mg empagliflozin with 5 mg linagliptin | Oral |  | Glyxambi | BY | MP | C7524 C7556 C14885 | P7524 P7556 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C7556 C14885 | P7556 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C7524 C7556 C14885 | P14885 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C7556 C14885 | P14885 | 60 | 5 | 30 |  |  |
|  | Tablet containing 25 mg empagliflozin with 5 mg linagliptin | Oral |  | Glyxambi | BY | MP | C7524 C7556 C14885 | P7524 P7556 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C7556 C14885 | P7556 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C7524 C7556 C14885 | P14885 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C7556 C14885 | P14885 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Empagliflozin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Empagliflozin with metformin | Tablet containing 5 mg empagliflozin with 1 g metformin hydrochloride | Oral |  | Jardiamet 5 mg/1000 mg | BY | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P5657 P5798 P5953 P5966 P7492 P7498 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P5657 P5798 P5966 P7492 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  | Tablet containing 5 mg empagliflozin with 500 mg metformin hydrochloride | Oral |  | Jardiamet 5 mg/500 mg | BY | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P5657 P5798 P5953 P5966 P7492 P7498 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P5657 P5798 P5966 P7492 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  | Tablet containing 12.5 mg empagliflozin with 1 g metformin hydrochloride | Oral |  | Jardiamet 12.5 mg/1000 mg | BY | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P5657 P5798 P5953 P5966 P7492 P7498 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P5657 P5798 P5966 P7492 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  | Tablet containing 12.5 mg empagliflozin with 500 mg metformin hydrochloride | Oral |  | Jardiamet 12.5 mg/500 mg | BY | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P5657 P5798 P5953 P5966 P7492 P7498 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P5657 P5798 P5966 P7492 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C5657 C5798 C5953 C5966 C7492 C7498 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C5657 C5798 C5966 C7492 C14878 C14881 C14924 C14925 | P14878 P14881 P14924 P14925 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Eprosartan**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Eprosartan | Tablet 600 mg (as mesilate) | Oral |  | Teveten | GO | MP NP |  |  | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP |  | P6328 P6329 P6332 P6351 | 28 CN6328 CN6329 CN6332 CN6351 | 5 CN6328 CN6329 CN6332 CN6351 | 28 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP |  | P14841 P14969 P14970 P15009 | 56  CN14841 CN14969 CN14970 CN15009 | 5  CN14841 CN14969 CN14970 CN15009 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol in the form Transdermal gel 1 mg (as hemihydrate) in 1 g sachet, 28**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal gel 1 mg (as hemihydrate) in 1 g sachet, 28 | Transdermal |  | Sandrena | OX | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol in the form Pessary (modified release) 10 micrograms (as hemihydrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Pessary (modified release) 10 micrograms (as hemihydrate) | Vaginal | a | Estro-Pess | AS | MP NP |  |  | 18 | 2 | 18 |  |  |
|  |  |  | a | Vagifem Low | NO | MP NP |  |  | 18 | 2 | 18 |  |  |
|  |  |  | a | Estro-Pess | AS | MP NP |  | P14238 | 36 | 2 | 18 |  |  |
|  |  |  | a | Vagifem Low | NO | MP NP |  | P14238 | 36 | 2 | 18 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol in the form Tablet containing estradiol valerate 1 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing estradiol valerate 1 mg | Oral |  | Progynova | BN | MP NP |  |  | 56 | 2 | 56 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 112 | 2 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol in the form Tablet 2 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 2 mg | Oral |  | Zumenon | GO | MP NP |  |  | 56 | 2 | 56 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 112 | 2 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol in the form Tablet containing estradiol valerate 2 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing estradiol valerate 2 mg | Oral |  | Progynova | BN | MP NP |  |  | 56 | 2 | 56 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 112 | 2 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol and estradiol with dydrogesterone**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol and estradiol with dydrogesterone | Pack containing 14 tablets estradiol 1 mg and 14 tablets estradiol 1 mg with dydrogesterone 10 mg | Oral |  | Femoston 1/10 | GO | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |
|  | Pack containing 14 tablets estradiol 2 mg and 14 tablets estradiol 2 mg with dydrogesterone 10 mg | Oral |  | Femoston 2/10 | GO | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol and estradiol with norethisterone**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estradiol and estradiol with norethisterone | Pack containing 4 transdermal patches 780 micrograms estradiol (as hemihydrate) and 4 transdermal patches 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate | Transdermal |  | Estalis sequi 50/250 | SZ | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |
|  | Pack containing 4 transdermal patches 780 micrograms estradiol (as hemihydrate) and 4 transdermal patches 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate | Transdermal |  | Estalis sequi 50/140 | SZ | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Estradiol with norethisterone in the form Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 | Transdermal |  | Estalis continuous 50/140 | SZ | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Estriol**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Estriol | Vaginal cream 1 mg per g, 15 g | Application |  | Ovestin | AS | MP NP |  |  | 1 | 1 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 1 | 1 |  |  |
|  | Pessaries 500 micrograms, 15 | Vaginal |  | Ovestin Ovula | AS | MP NP |  |  | 1 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 2 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Ethosuximide in the form Oral solution 250 mg per 5 mL, 200 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Oral solution 250 mg per 5 mL, 200 mL | Oral |  | Zarontin | IX | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Everolimus in the form Tablet 0.75 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 0.75 mg | Oral | a | Certican | NV | MP |  |  | 120 | 3 | 60 |  |  |
|  |  |  | a | Everocan | CR | MP |  |  | 120 | 3 | 60 |  |  |
|  |  |  | a | Certican | NV | MP |  | P14238 | 240 | 3 | 60 |  |  |
|  |  |  | a | Everocan | CR | MP |  | P14238 | 240 | 3 | 60 |  |  |
|  |  |  | a | Certican | NV | MP |  | P5554 P5795 P9691 P9693 | 240 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 60 |  | C(100) |
|  |  |  | a | Everocan | CR | MP |  | P5554 P5795 P9691 P9693 | 240 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 60 |  | C(100) |

1. **Schedule 1, Part 1, entry for Everolimus in the form Tablet 1 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 1 mg | Oral | a | Certican | NV | MP |  |  | 120 | 3 | 60 |  |  |
|  |  |  | a | Everocan | CR | MP |  |  | 120 | 3 | 60 |  |  |
|  |  |  | a | Certican | NV | MP |  | P14238 | 240 | 3 | 60 |  |  |
|  |  |  | a | Everocan | CR | MP |  | P14238 | 240 | 3 | 60 |  |  |
|  |  |  | a | Certican | NV | MP |  | P5554 P5795 P9691 P9693 | 240 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 60 |  | C(100) |
|  |  |  | a | Everocan | CR | MP |  | P5554 P5795 P9691 P9693 | 240 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 60 |  | C(100) |

1. **Schedule 1, Part 1, entry for Exemestane**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Exemestane | Tablet 25 mg | Oral | a | APO-Exemestane | TX | MP | C4796 C5522 C14992 C15031 | P4796 P5522 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P5522 | 30 | 5 | 30 |  |  |
|  |  |  | a | Aromasin | PF | MP | C4796 C5522 C14992 C15031 | P4796 P5522 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P5522 | 30 | 5 | 30 |  |  |
|  |  |  | a | Exemestane GH | GQ | MP | C4796 C5522 C14992 C15031 | P4796 P5522 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P5522 | 30 | 5 | 30 |  |  |
|  |  |  | a | Exemestane Sandoz | SZ | MP | C4796 C5522 C14992 C15031 | P4796 P5522 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P5522 | 30 | 5 | 30 |  |  |
|  |  |  | a | APO-Exemestane | TX | MP | C4796 C5522 C14992 C15031 | P14992 P15031 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P14992 | 60 | 5 | 30 |  |  |
|  |  |  | a | Aromasin | PF | MP | C4796 C5522 C14992 C15031 | P14992 P15031 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P14992 | 60 | 5 | 30 |  |  |
|  |  |  | a | Exemestane GH | GQ | MP | C4796 C5522 C14992 C15031 | P14992 P15031 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P14992 | 60 | 5 | 30 |  |  |
|  |  |  | a | Exemestane Sandoz | SZ | MP | C4796 C5522 C14992 C15031 | P14992 P15031 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C5522 C14992 | P14992 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Glibenclamide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Glibenclamide | Tablet 5 mg | Oral |  | Daonil | SW | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Gliclazide in the form Tablet 60 mg (modified release)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 60 mg (modified release) | Oral | a | ARDIX GLICLAZIDE 60mg MR | XT | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Diamicron 60mg MR | SE | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Gliclazide Lupin MR | GQ | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Pharmacor Gliclazide MR | CR | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | ARDIX GLICLAZIDE 60mg MR | XT | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Diamicron 60mg MR | SE | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Gliclazide Lupin MR | GQ | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Pharmacor Gliclazide MR | CR | MP NP |  | P14238 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Gliclazide in the form Tablet 80 mg (modified release)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 80 mg | Oral | a | APO-Gliclazide | TX | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | APX-Gliclazide | TY | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Glyade | AF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Nidem | RW | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | APO-Gliclazide | TX | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | APX-Gliclazide | TY | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Glyade | AF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Nidem | RW | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Glimepiride**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Glimepiride | Tablet 1 mg | Oral | a | Amaryl | SW | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Aylide 1 | AF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Amaryl | SW | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Aylide 1 | AF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  | Tablet 2 mg | Oral | a | Aylide 2 | AF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Aylide 2 | AF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  | Tablet 3 mg | Oral | a | Aylide 3 | AF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Aylide 3 | AF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  | Tablet 4 mg | Oral | a | Aylide 4 | AF | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  |  | 30 | 5 | 30 |  |  |
|  |  |  | a | Aylide 4 | AF | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride APOTEX | GX | MP NP |  | P14238 | 60 | 5 | 30 |  |  |
|  |  |  | a | Glimepiride Sandoz | SZ | MP NP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Glipizide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Glipizide | Tablet 5 mg | Oral | a | Melizide | AF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Minidiab | PF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Melizide | AF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Minidiab | PF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Hydrocortisone in the form Tablet 4 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hydrocortisone | Tablet 4 mg | Oral | a | Hydrocortisone Viatris 4 | AL | MP NP |  |  | 50 | 4 | 50 |  |  |
|  |  |  | a | Hysone 4 | AF | MP NP |  |  | 50 | 4 | 50 |  |  |
|  |  |  | a | Hydrocortisone Viatris 4 | AL | MP NP |  | P14238 | 100 | 4 | 50 |  |  |
|  |  |  | a | Hysone 4 | AF | MP NP |  | P14238 | 100 | 4 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Labetalol**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Labetalol | Tablet containing labetalol hydrochloride 100 mg | Oral |  | Presolol 100 | AF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Lacosamide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lacosamide | Oral solution 10 mg per mL, 200 mL | Oral |  | Vimpat | UC | MP NP | C8770 C8815 C12092 C14853 C14857 | P12092 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 | 4 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 | 6 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C8770 C8815 C12092 C14853 C14857 | P14857 | 12 | 5 | 1 |  |  |
|  | Tablet 50 mg | Oral | a | Lacoress | LR | MP NP | C8813 |  | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Vimcosa | CR | MP NP | C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Vimpat | UC | MP NP | C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8813 C8815 C12092 C14853 C14857 | P8815 P12092 | 56 | 5 | 14 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8813 C8815 C12092 C14853 C14857 | P8815 P12092 | 56 | 5 | 14 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8813 C8815 C12092 C14853 C14857 | P8815 P12092 | 56 | 5 | 14 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8813 C8815 C12092 C14853 C14857 | P8815 P12092 | 56 | 5 | 14 |  |  |
|  |  |  | a | Vimcosa | CR | MP NP | C8813 C8815 C12092 C14853 C14857 | P8815 P12092 | 56 | 5 | 14 |  |  |
|  |  |  | a | Vimpat | UC | MP NP | C8813 C8815 C12092 C14853 C14857 | P8815 P12092 | 56 | 5 | 14 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 14 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 14 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 14 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 14 |  |  |
|  |  |  | a | Vimcosa | CR | MP NP | C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 14 |  |  |
|  |  |  | a | Vimpat | UC | MP NP | C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 14 |  |  |
|  | Tablet 100 mg | Oral | a | Lacoress | LR | MP NP | C8770 C8813 C8815 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8813 P12225 | 14 | 1 | 14 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Vimcosa | CR | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8813 P12225 | 14 | 1 | 14 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Vimpat | UC | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8813 P12225 | 14 | 1 | 14 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacoress | LR | MP NP | C8770 C8813 C8815 C14857 | P8770 P8815 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Vimcosa | CR | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Vimpat | UC | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacoress | LR | MP NP | C8770 C8813 C8815 C14857 | P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Vimcosa | CR | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Vimpat | UC | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  | Tablet 150 mg | Oral | a | Lacoress | LR | MP NP | C8770 C8813 C8815 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Vimcosa | CR | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8813 P12225 | 14 | 1 | 14 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Vimpat | UC | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8813 P12225 | 14 | 1 | 14 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8813 | 14 | 1 | 14 |  |  |
|  |  |  | a | Lacoress | LR | MP NP | C8770 C8813 C8815 C14857 | P8770 P8815 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Vimcosa | CR | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Vimpat | UC | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacoress | LR | MP NP | C8770 C8813 C8815 C14857 | P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Vimcosa | CR | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Vimpat | UC | MP | C8770 C8813 C8815 C12092 C12225 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C8770 C8813 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  | Tablet 200 mg | Oral | a | Lacoress | LR | MP NP | C8770 C8815 C14857 | P8770 P8815 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Vimcosa | CR | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Vimpat | UC | MP NP | C8770 C8815 C12092 C14853 C14857 | P8770 P8815 P12092 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lacoress | LR | MP NP | C8770 C8815 C14857 | P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosam | AF | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide ARX | XT | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Lupin | GQ | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lacosamide Sandoz | SZ | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Vimcosa | CR | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |
|  |  |  | a | Vimpat | UC | MP NP | C8770 C8815 C12092 C14853 C14857 | P14853 P14857 | 112 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Lamotrigine**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lamotrigine | Tablet 5 mg | Oral |  | Lamictal | AS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  | Tablet 25 mg | Oral | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Reedos 25 | ZS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Reedos 25 | ZS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  | Tablet 50 mg | Oral | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Reedos 50 | ZS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Reedos 50 | ZS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  | Tablet 100 mg | Oral | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Reedos 100 | ZS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Reedos 100 | ZS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  | Tablet 200 mg | Oral | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Reedos 200 | ZS | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P11081 | 56 | 5 | 56 |  |  |
|  |  |  | a | APX-Lamotrigine | TY | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamictal | AS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | LAMITAN | RF | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Lamotrigine GH | GQ | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Logem | AL | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | NOUMED LAMOTRIGINE | VO | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Reedos 200 | ZS | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sandoz Lamotrigine | HX | MP NP | C11081 C14855 | P14855 | 112 | 5 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Lanthanum**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lanthanum | Tablet, chewable, 500 mg (as carbonate hydrate) | Oral |  | Fosrenol | TK | MP NP | C5491 C14872 | P5491 | 90 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP NP | C5491 C14872 | P14872 | 180 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 180 | 5 | 90 |  | C(100) |
|  | Tablet, chewable, 750 mg (as carbonate hydrate) | Oral |  | Fosrenol | TK | MP NP | C5491 C14872 | P5491 | 90 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP NP | C5491 C14872 | P14872 | 180 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 180 | 5 | 90 |  | C(100) |
|  | Tablet, chewable, 1000 mg (as carbonate hydrate) | Oral |  | Fosrenol | TK | MP NP | C5491 C14872 | P5491 | 90 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP NP | C5491 C14872 | P14872 | 180 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 180 | 5 | 90 |  | C(100) |

1. **Schedule 1, Part 1, entry for Leflunomide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Leflunomide | Tablet 10 mg | Oral | a | Arabloc | AV | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Arava | SW | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Ataris 10 | AF | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide APOTEX | GX | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide generichealth | HQ | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide Sandoz | SZ | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Lunava 10 | RW | MP | C13753 C14942 | P13753 | 30 | 5 | 30 |  |  |
|  |  |  | a | Arabloc | AV | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Arava | SW | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Ataris 10 | AF | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide APOTEX | GX | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide generichealth | HQ | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide Sandoz | SZ | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Lunava 10 | RW | MP | C13753 C14942 | P14942 | 60 | 5 | 30 |  |  |
|  | Tablet 20 mg | Oral | a | Arava | SW | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Ataris 20 | AF | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide APOTEX | GX | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide generichealth | HQ | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide Sandoz | SZ | MP | C13753 C13771 C14941 C14942 | P13753 P13771 | 30 | 5 | 30 |  |  |
|  |  |  | a | Lunava 20 | RW | MP | C13753 C14942 | P13753 | 30 | 5 | 30 |  |  |
|  |  |  | a | Arava | SW | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Ataris 20 | AF | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide APOTEX | GX | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide generichealth | HQ | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Leflunomide Sandoz | SZ | MP | C13753 C13771 C14941 C14942 | P14941 P14942 | 60 | 5 | 30 |  |  |
|  |  |  | a | Lunava 20 | RW | MP | C13753 C14942 | P14942 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Letrozole**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Letrozole | Tablet 2.5 mg | Oral | a | Femara 2.5 mg | NV | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Femolet | AF | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Gynotril | ZS | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Letrozole APOTEX | GX | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Letrozole GH | HQ | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Letrozole Sandoz | SZ | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Letrozole 2.5 | CR | MP NP | C5464 C14943 | P5464 | 30 | 5 | 30 |  |  |
|  |  |  | a | Femara 2.5 mg | NV | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Femolet | AF | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Gynotril | ZS | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Letrozole APOTEX | GX | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Letrozole GH | HQ | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Letrozole Sandoz | SZ | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Letrozole 2.5 | CR | MP NP | C5464 C14943 | P14943 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Levetiracetam**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Levetiracetam | Oral solution 100 mg per mL, 300 mL | Oral | a | APO-Levetiracetam | TX | MP NP | C11077 C14988 | P11077 | 1 | 5 | 1 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11077 C14988 | P11077 | 1 | 5 | 1 |  |  |
|  |  |  | a | Kerron | ZS | MP NP | C11077 C14988 | P11077 | 1 | 5 | 1 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11077 C14988 | P11077 | 1 | 5 | 1 |  |  |
|  |  |  | a | Levetiracetam-AFT | AE | MP NP | C11077 C14988 | P11077 | 1 | 5 | 1 |  |  |
|  |  |  | a | APO-Levetiracetam | TX | MP NP | C11077 C14988 | P14988 | 2 | 5 | 1 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11077 C14988 | P14988 | 2 | 5 | 1 |  |  |
|  |  |  | a | Kerron | ZS | MP NP | C11077 C14988 | P14988 | 2 | 5 | 1 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11077 C14988 | P14988 | 2 | 5 | 1 |  |  |
|  |  |  | a | Levetiracetam-AFT | AE | MP NP | C11077 C14988 | P14988 | 2 | 5 | 1 |  |  |
|  | Tablet 250 mg | Oral | a | APO-Levetiracetam | TX | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Kevtam 250 | AF | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levactam | ZS | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levecetam 250 | RZ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam Mylan | AL | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam SZ | SZ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levi 250 | RW | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED LEVETIRACETAM | VO | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Levetiracetam | TX | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Kevtam 250 | AF | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levactam | ZS | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levecetam 250 | RZ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam Mylan | AL | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam SZ | SZ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levi 250 | RW | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED LEVETIRACETAM | VO | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  | Tablet 500 mg | Oral | a | APO-Levetiracetam | TX | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Kevtam 500 | AF | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levactam | ZS | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levecetam 500 | RZ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam Mylan | AL | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam SZ | SZ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levi 500 | RW | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED LEVETIRACETAM | VO | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Levetiracetam | TX | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Kevtam 500 | AF | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levactam | ZS | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levecetam 500 | RZ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam Mylan | AL | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam SZ | SZ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levi 500 | RW | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED LEVETIRACETAM | VO | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  | Tablet 1 g | Oral | a | APO-Levetiracetam | TX | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Kevtam 1000 | AF | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levactam | ZS | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levecetam 1000 | RZ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam Mylan | AL | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam SZ | SZ | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | Levi 1000 | RW | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED LEVETIRACETAM | VO | MP NP | C11116 C14964 | P11116 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Levetiracetam | TX | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Keppra | UC | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Kevtam 1000 | AF | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levactam | ZS | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levecetam 1000 | RZ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam GH | GQ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam Mylan | AL | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levetiracetam SZ | SZ | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | Levi 1000 | RW | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED LEVETIRACETAM | VO | MP NP | C11116 C14964 | P14964 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Linagliptin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Linagliptin | Tablet 5 mg | Oral |  | Trajenta | BY | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Linagliptin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride | Oral |  | Trajentamet | BY | MP | C6333 C6336 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14935 | P6333 P6336 P6344 P6443 P7507 P7530 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C6333 C6336 C6344 C6443 C7530 C14888 C14891 C14894 C14935 | P6333 P6336 P6344 P6443 P7530 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C6333 C6336 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14935 | P14888 P14891 P14894 P14935 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C6333 C6336 C6344 C6443 C7530 C14888 C14891 C14894 C14935 | P14888 P14891 P14894 P14935 | 120 | 5 | 60 |  |  |
|  | Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride | Oral |  | Trajentamet | BY | MP | C6333 C6336 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14935 | P6333 P6336 P6344 P6443 P7507 P7530 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C6333 C6336 C6344 C6443 C7530 C14888 C14891 C14894 C14935 | P6333 P6336 P6344 P6443 P7530 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C6333 C6336 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14935 | P14888 P14891 P14894 P14935 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C6333 C6336 C6344 C6443 C7530 C14888 C14891 C14894 C14935 | P14888 P14891 P14894 P14935 | 120 | 5 | 60 |  |  |
|  | Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride | Oral |  | Trajentamet | BY | MP | C6333 C6336 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14935 | P6333 P6336 P6344 P6443 P7507 P7530 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C6333 C6336 C6344 C6443 C7530 C14888 C14891 C14894 C14935 | P6333 P6336 P6344 P6443 P7530 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP | C6333 C6336 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14935 | P14888 P14891 P14894 P14935 | 120 | 5 | 60 |  |  |
|  |  |  |  |  |  | NP | C6333 C6336 C6344 C6443 C7530 C14888 C14891 C14894 C14935 | P14888 P14891 P14894 P14935 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Liothyronine**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Liothyronine | Tablet containing liothyronine sodium 20 micrograms | Oral |  | Tertroxin | AS | MP NP | C6382 C6410 C6475 C14843 C14844 C15038 | P6382 P6410 P6475 | 100 | 2 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C6382 C6410 C6475 C14843 C14844 C15038 | P14843 P14844 P15038 | 200 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 5 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing medroxyprogesterone acetate 5 mg | Oral | a | Provera | PF | MP NP |  |  | 56 | 2 | 56 |  |  |
|  |  |  | a | Ralovera | FZ | MP NP |  |  | 56 | 2 | 56 |  |  |
|  |  |  | a | Provera | PF | MP NP |  | P14238 | 112 | 2 | 56 |  |  |
|  |  |  | a | Ralovera | FZ | MP NP |  | P14238 | 112 | 2 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 10 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing medroxyprogesterone acetate 10 mg | Oral | a | Provera | PF | MP NP |  |  | 30 | 2 | 30 |  |  |
|  |  |  | a | Ralovera | FZ | MP NP |  |  | 30 | 2 | 30 |  |  |
|  |  |  | a | Provera | PF | MP NP |  | P14238 | 60 | 2 | 30 |  |  |
|  |  |  | a | Ralovera | FZ | MP NP |  | P14238 | 60 | 2 | 30 |  |  |
|  |  |  | a | Provera | PF | MP |  | P6244 | 100 | 2 | 100 |  |  |
|  |  |  | a | Ralovera | FZ | MP |  | P6244 | 100 | 2 | 100 |  |  |
|  |  |  | a | Provera | PF | MP |  | P15030 | 200 | 2 | 100 |  |  |
|  |  |  | a | Ralovera | FZ | MP |  | P15030 | 200 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 100 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing medroxyprogesterone acetate 100 mg | Oral |  | Provera | PF | MP | C5649 C5791 C14965 C14990 | P5649 P5791 | 100 | 2 | 100 |  |  |
|  |  |  |  |  |  | MP | C5649 C5791 C14965 C14990 | P14965 P14990 | 200 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 200 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing medroxyprogesterone acetate 200 mg | Oral |  | Provera | PF | MP | C5649 C5791 C14965 C14990 | P5649 P5791 | 60 | 2 | 60 |  |  |
|  |  |  |  |  |  | MP | C5649 C5791 C14965 C14990 | P14965 P14990 | 120 | 2 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 250 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing medroxyprogesterone acetate 250 mg | Oral |  | Provera | PF | MP | C5649 C5791 C14965 C14990 | P5649 P5791 | 60 | 2 | 60 |  |  |
|  |  |  |  |  |  | MP | C5649 C5791 C14965 C14990 | P14965 P14990 | 120 | 2 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Medroxyprogesterone in the form Tablet containing medroxyprogesterone acetate 500 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing medroxyprogesterone acetate 500 mg | Oral |  | Provera | PF | MP | C5731 C15007 | P5731 | 30 | 2 | 30 |  |  |
|  |  |  |  |  |  | MP | C5731 C15007 | P15007 | 60 | 2 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metformin | Tablet (extended release) containing metformin hydrochloride 500 mg | Oral | a | APO-Metformin XR 500 | TX | MP NP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Blooms the Chemist Metformin XR 500 | IB | MP NP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Diabex XR 500 | AL | MP NP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Metex XR | RW | MP NP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Pharmacor Metformin XR | CR | MP NP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | APO-Metformin XR 500 | TX | MP NP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  | a | Blooms the Chemist Metformin XR 500 | IB | MP NP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  | a | Diabex XR 500 | AL | MP NP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  | a | Metex XR | RW | MP NP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  | a | Pharmacor Metformin XR | CR | MP NP |  | P14238 | 240 | 5 | 120 |  |  |
|  | Tablet containing metformin hydrochloride 500 mg | Oral | a | APX-Metformin | TY | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Blooms The Chemist Metformin 500 mg | BG | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Diabex | AL | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Diaformin | AF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | FORMET 500 | RF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Glucobete 500 | ZS | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Metformin GH | HQ | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Metformin Sandoz | SZ | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | APX-Metformin | TY | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Blooms The Chemist Metformin 500 mg | BG | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Diabex | AL | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Diaformin | AF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | FORMET 500 | RF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Glucobete 500 | ZS | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Metformin GH | HQ | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Metformin Sandoz | SZ | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  | Tablet containing metformin hydrochloride 850 mg | Oral | a | APX-Metformin | TY | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Blooms The Chemist Metformin 850 mg | BG | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Diabex 850 | AL | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Diaformin 850 | AF | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | FORMET 850 | RF | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Glucobete 850 | ZS | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Metformin Sandoz | SZ | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | APX-Metformin | TY | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Blooms The Chemist Metformin 850 mg | BG | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Diabex 850 | AL | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Diaformin 850 | AF | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | FORMET 850 | RF | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Glucobete 850 | ZS | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Metformin Sandoz | SZ | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  | Tablet (extended release) containing metformin hydrochloride 1 g | Oral | a | APO-Metformin XR 1000 | TX | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Blooms the Chemist Metformin XR 1000 | IB | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Diabex XR 1000 | AL | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Diaformin XR 1000 | AF | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | METEX XR | RF | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | Pharmacor Metformin XR | CR | MP NP |  |  | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Metformin XR 1000 | TX | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Blooms the Chemist Metformin XR 1000 | IB | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Diabex XR 1000 | AL | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Diaformin XR 1000 | AF | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | METEX XR | RF | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  |  |  | a | Pharmacor Metformin XR | CR | MP NP |  | P14238 | 120 | 5 | 60 |  |  |
|  | Tablet containing metformin hydrochloride 1 g | Oral | a | APX-Metformin | TY | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Blooms The Chemist Metformin 1000 mg | BG | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Diabex 1000 | AL | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Diaformin 1000 | AF | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Formet 1000 | RW | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Glucobete 1000 | ZS | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Metformin GH | HQ | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | Metformin Sandoz | SZ | MP NP |  |  | 90 | 5 | 90 |  |  |
|  |  |  | a | APX-Metformin | TY | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Blooms The Chemist Metformin 1000 mg | BG | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Diabex 1000 | AL | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Diaformin 1000 | AF | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Formet 1000 | RW | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Glucobete 1000 | ZS | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Metformin GH | HQ | MP NP |  | P14238 | 180 | 5 | 90 |  |  |
|  |  |  | a | Metformin Sandoz | SZ | MP NP |  | P14238 | 180 | 5 | 90 |  |  |

1. **Schedule 1, Part 1, entry for Methenamine**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Methenamine | Tablet containing methenamine hippurate 1 g | Oral | a | Hiprex | IL | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Uramet | AS | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Hiprex | IL | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Uramet | AS | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Methotrexate in the form Injection 50 mg in 2 mL vial**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Injection 50 mg in 2 mL vial | Injection |  | DBL Methotrexate | PF | MP |  |  | 5 | 5 | 5 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 10 | 5 | 5 |  |  |
|  |  |  |  |  |  | MP |  |  | See Note 2 | See Note 2 | 5 |  | C(100) |
|  |  |  |  |  |  | MP |  | P6276 | See Note 2 | See Note 2 | 5 |  | C(100) |

1. **Schedule 1, Part 1, entry for Minoxidil in the form Tablet 10 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Minoxidil | Tablet 10 mg | Oral |  | Loniten | PF | MP NP | C5177 C14994 | P5177 | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C5177 C14994 | P14994 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Mycophenolic acid**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mycophenolic acid | Capsule containing mycophenolate mofetil 250 mg | Oral | a | Ceptolate | AF | MP |  |  | 300 | 5 | 50 |  |  |
|  |  |  | a | APO-Mycophenolate | TX | MP |  |  | 300 | 5 | 100 |  |  |
|  |  |  | a | CellCept | RO | MP |  |  | 300 | 5 | 100 |  |  |
|  |  |  | a | Mycophenolate Sandoz | SZ | MP |  |  | 300 | 5 | 100 |  |  |
|  |  |  | a | Pharmacor Mycophenolate 250 | CR | MP |  |  | 300 | 5 | 100 |  |  |
|  |  |  | a | Ceptolate | AF | MP |  | P14238 | 600 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5600 P5653 P9689 P9690 | 600 CN5600 CN5653 CN9689 CN9690 | 5 CN5600 CN5653 CN9689 CN9690 | 50 |  | C(100) |
|  |  |  | a | APO-Mycophenolate | TX | MP |  | P14238 | 600 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5600 P5653 P9689 P9690 | 600 CN5600 CN5653 CN9689 CN9690 | 5 CN5600 CN5653 CN9689 CN9690 | 100 |  | C(100) |
|  |  |  | a | CellCept | RO | MP |  | P14238 | 600 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5600 P5653 P9689 P9690 | 600 CN5600 CN5653 CN9689 CN9690 | 5 CN5600 CN5653 CN9689 CN9690 | 100 |  | C(100) |
|  |  |  | a | Mycophenolate Sandoz | SZ | MP |  | P14238 | 600 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5600 P5653 P9689 P9690 | 600 CN5600 CN5653 CN9689 CN9690 | 5 CN5600 CN5653 CN9689 CN9690 | 100 |  | C(100) |
|  |  |  | a | Pharmacor Mycophenolate 250 | CR | MP |  | P14238 | 600 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5600 P5653 P9689 P9690 | 600 CN5600 CN5653 CN9689 CN9690 | 5 CN5600 CN5653 CN9689 CN9690 | 100 |  | C(100) |
|  | Powder for oral suspension containing mycophenolate mofetil 1 g per 5 mL, 165 mL | Oral | a | CellCept | RO | MP |  |  | 1 | 5 | 1 |  |  |
|  |  |  | a | Pharmacor Mycophenolate | CR | MP |  |  | 1 | 5 | 1 |  |  |
|  |  |  | a | CellCept | RO | MP |  | P14238 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 2 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 1 |  | C(100) |
|  |  |  | a | Pharmacor Mycophenolate | CR | MP |  | P14238 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 2 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 1 |  | C(100) |
|  | Tablet (enteric coated) containing mycophenolate sodium equivalent to 180 mg mycophenolic acid | Oral | a | Mycophenolic Acid ARX | XT | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Myfortic | NV | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Mycophenolic Acid ARX | XT | MP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  |  |  |  | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | Myfortic | NV | MP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  |  |  |  | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  | Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid | Oral | a | Mycophenolic Acid ARX | XT | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | MYCOTEX | CR | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Myfortic | NV | MP |  |  | 120 | 5 | 120 |  |  |
|  |  |  | a | Mycophenolic Acid ARX | XT | MP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  |  |  |  | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | MYCOTEX | CR | MP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  |  |  |  | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  |  |  | a | Myfortic | NV | MP |  | P14238 | 240 | 5 | 120 |  |  |
|  |  |  |  |  |  | MP |  | P4084 P4095 P9692 P9809 | 240 CN4084 CN4095 CN9692 CN9809 | 5 CN4084 CN4095 CN9692 CN9809 | 120 |  | C(100) |
|  | Tablet containing mycophenolate mofetil 500 mg | Oral | a | CellCept | RO | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | Ceptolate | AF | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | MycoCept | RF | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | Mycophenolate APOTEX | GX | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | Mycophenolate GH | GQ | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | Mycophenolate Sandoz | SZ | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | Noumed Mycophenolate | VO | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | Pharmacor Mycophenolate 500 | CR | MP |  |  | 150 | 5 | 50 |  |  |
|  |  |  | a | CellCept | RO | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | Ceptolate | AF | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | MycoCept | RF | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | Mycophenolate APOTEX | GX | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | Mycophenolate GH | GQ | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | Mycophenolate Sandoz | SZ | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | Noumed Mycophenolate | VO | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |
|  |  |  | a | Pharmacor Mycophenolate 500 | CR | MP |  | P14238 | 300 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5554 P5795 P9691 P9693 | 300 CN5554 CN5795 CN9691 CN9693 | 5 CN5554 CN5795 CN9691 CN9693 | 50 |  | C(100) |

1. **Schedule 1, Part 1, entry for Norethisterone in the form Tablet 5 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Norethisterone | Tablet 5 mg | Oral |  | Primolut N | BN | MP NP |  |  | 30 | 2 | 30 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 60 | 2 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) | Oral | a | OLMEKAR | RW | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 40/5 | AF | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 40/5 APOTEX | TX | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/5 | CR | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 40/5 | AL | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | OLMEKAR | RW | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 40/5 | AF | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 40/5 APOTEX | TX | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/5 | CR | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 40/5 | AL | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan with amlodipine in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) | Oral | a | OLMEKAR | RW | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 40/10 | AF | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 40/10 APOTEX | TX | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/10 | CR | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 40/10 | AL | MP NP | C4373 C14839 | P4373 | 30 | 5 | 30 |  |  |
|  |  |  | a | OLMEKAR | RW | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine - MYL 40/10 | AF | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine 40/10 APOTEX | TX | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmesartan/Amlodipine Sandoz | SZ | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Pharmacor Olmesartan Amlodipine 40/10 | CR | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |
|  |  |  | a | Sevikar 40/10 | AL | MP NP | C4373 C14839 | P14839 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Olmesartan with amlodipine and hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg | Oral | a | APO-Olmesartan/Amlodipine/HCTZ 40/10/25 | TX | MP NP | C4311 C14837 | P4311 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olamlo HCT 40/10/25 | AL | MP NP | C4311 C14837 | P4311 | 30 | 5 | 30 |  |  |
|  |  |  | a | Olmekar HCT 40/10/25 | RF | MP NP | C4311 C14837 | P4311 | 30 | 5 | 30 |  |  |
|  |  |  | a | Sevikar HCT 40/10/25 | AF | MP NP | C4311 C14837 | P4311 | 30 | 5 | 30 |  |  |
|  |  |  | a | APO-Olmesartan/Amlodipine/HCTZ 40/10/25 | TX | MP NP | C4311 C14837 | P14837 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olamlo HCT 40/10/25 | AL | MP NP | C4311 C14837 | P14837 | 60 | 5 | 30 |  |  |
|  |  |  | a | Olmekar HCT 40/10/25 | RF | MP NP | C4311 C14837 | P14837 | 60 | 5 | 30 |  |  |
|  |  |  | a | Sevikar HCT 40/10/25 | AF | MP NP | C4311 C14837 | P14837 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Oxcarbazepine in the form Oral suspension 60 mg per mL, 250 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Oxcarbazepine | Oral suspension 60 mg per mL, 250 mL | Oral |  | Trileptal | NV | MP NP | C5183 C14932 | P5183 | 2 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C5183 C14932 | P14932 | 4 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Oxcarbazepine in the form Tablet 300 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 300 mg | Oral |  | Trileptal | NV | MP NP | C5183 C14932 | P5183 | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C5183 C14932 | P14932 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Oxcarbazepine in the form Tablet 600 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 600 mg | Oral |  | Trileptal | NV | MP NP | C5183 C14932 | P5183 | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C5183 C14932 | P14932 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Oxybutynin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Oxybutynin | Transdermal patches 36 mg, 8 | Transdermal |  | Oxytrol | TT | MP NP | C6243 C15006 | P6243 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP NP | C6243 C15006 | P15006 | 2 | 5 | 1 |  |  |
|  | Tablet containing oxybutynin hydrochloride 5 mg | Oral |  | Ditropan | SW | MP NP | C6241 C14915 | P6241 | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C6241 C14915 | P14915 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Perampanel in the form Tablet 4 mg (as hemisesquihydrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 4 mg (as hemisesquihydrate) | Oral |  | Fycompa | EI | MP NP | C4658 C7789 C14847 C14852 | P7789 | 28 | 2 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P4658 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14847 | 56 | 2 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14852 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Perampanel in the form Tablet 6 mg (as hemisesquihydrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 6 mg (as hemisesquihydrate) | Oral |  | Fycompa | EI | MP NP | C4658 C7789 C14847 C14852 | P7789 | 28 | 2 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P4658 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14847 | 56 | 2 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14852 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Perampanel in the form Tablet 8 mg (as hemisesquihydrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 8 mg (as hemisesquihydrate) | Oral |  | Fycompa | EI | MP NP | C4658 C7789 C14847 C14852 | P4658 P7789 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14847 P14852 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Perampanel in the form Tablet 10 mg (as hemisesquihydrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 10 mg (as hemisesquihydrate) | Oral |  | Fycompa | EI | MP NP | C4658 C7789 C14847 C14852 | P4658 P7789 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14847 P14852 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Perampanel in the form Tablet 12 mg (as hemisesquihydrate)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 12 mg (as hemisesquihydrate) | Oral |  | Fycompa | EI | MP NP | C4658 C7789 C14847 C14852 | P4658 P7789 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP NP | C4658 C7789 C14847 C14852 | P14847 P14852 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Phenoxymethylpenicillin in the form Capsule 250 mg phenoxymethylpenicillin (as potassium)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phenoxymethylpenicillin | Capsule 250 mg phenoxymethylpenicillin (as potassium) | Oral |  | Cilicaine VK | AF | MP NP PDP |  |  | 50 | 0 | 50 |  |  |
|  |  |  |  | LPV | IL | MP NP PDP |  |  | 50 | 0 | 50 |  |  |
|  |  |  |  | Cilicaine VK | AF | MP NP |  | P5697 | 50 | 5 | 50 |  |  |
|  |  |  |  | LPV | IL | MP NP |  | P5697 | 50 | 5 | 50 |  |  |
|  |  |  |  | Cilicaine VK | AF | MP NP |  | P14947 | 100 | 5 | 50 |  |  |
|  |  |  |  | LPV | IL | MP NP |  | P14947 | 100 | 5 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Phenoxymethylpenicillin in the form Tablet 250 mg phenoxymethylpenicillin (as potassium)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 250 mg phenoxymethylpenicillin (as potassium) | Oral |  | Aspecillin VK | AF | MP NP PDP |  |  | 50 | 0 | 25 |  |  |
|  |  |  |  |  |  | MP NP |  | P5697 | 50 | 5 | 25 |  |  |
|  |  |  |  |  |  | MP NP |  | P14947 | 100 | 5 | 25 |  |  |

1. **Schedule 1, Part 1, entry for Phenytoin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phenytoin | Capsule containing phenytoin sodium 30 mg | Oral |  | Dilantin Sodium | UJ | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |
|  | Capsule containing phenytoin sodium 100 mg | Oral |  | Dilantin Sodium | UJ | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |
|  | Oral suspension 30 mg per 5 mL, 500 mL | Oral |  | Dilantin | UJ | MP NP |  |  | 1 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 2 | 3 | 1 |  |  |
|  | Tablet 50 mg | Oral |  | Dilantin Infatabs | UJ | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |

1. **Schedule 1, Part 1, entry for Pioglitazone**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pioglitazone | Tablet 15 mg (as hydrochloride) | Oral | a | Acpio 15 | RF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Actaze | RW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Actos | EW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | APOTEX-Pioglitazone | TX | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Vexazone | AF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Acpio 15 | RF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Actaze | RW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Actos | EW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | APOTEX-Pioglitazone | TX | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Vexazone | AF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  | Tablet 30 mg (as hydrochloride) | Oral | a | Acpio 30 | RF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Actaze | RW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Actos | EW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | APOTEX-Pioglitazone | TX | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | NOUMED PIOGLITAZONE | VO | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Pioglitazone Sandoz | SZ | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Vexazone | AF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Acpio 30 | RF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Actaze | RW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Actos | EW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | APOTEX-Pioglitazone | TX | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | NOUMED PIOGLITAZONE | VO | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Pioglitazone Sandoz | SZ | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Vexazone | AF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  | Tablet 45 mg (as hydrochloride) | Oral | a | Acpio 45 | RF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Actaze | RW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Actos | EW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | APOTEX-Pioglitazone | TX | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | NOUMED PIOGLITAZONE | VO | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Pioglitazone Sandoz | SZ | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Vexazone | AF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P4363 P4364 P4388 | 28 | 5 | 28 |  |  |
|  |  |  | a | Acpio 45 | RF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Actaze | RW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Actos | EW | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | APOTEX-Pioglitazone | TX | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | NOUMED PIOGLITAZONE | VO | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Pioglitazone Sandoz | SZ | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |
|  |  |  | a | Vexazone | AF | MP NP | C4363 C4364 C4388 C15001 C15002 C15014 | P15001 P15002 P15014 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Pizotifen**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pizotifen | Tablet 500 micrograms (as malate) | Oral |  | Sandomigran 0.5 | AE | MP NP |  |  | 100 | 2 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 200 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Prednisolone**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Prednisolone | Suppositories 5 mg (as sodium phosphate), 10 | Rectal |  | Predsol | AS | MP NP | C4872 C4893 |  | 3 | 3 | 1 |  |  |
|  | Enema, retention, 20 mg (as sodium phosphate) in 100 mL | Rectal |  | Predsol | AS | MP NP |  |  | 28 | 3 | 7 |  |  |
|  | Oral solution 5 mg (as sodium phosphate) per mL, 30 mL | Oral | a | PredMix | LN | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  | a | Redipred | AS | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  | a | PredMix | LN | MP NP |  | P14238 | 2 | 5 | 1 |  |  |
|  |  |  | a | Redipred | AS | MP NP |  | P14238 | 2 | 5 | 1 |  |  |
|  | Tablet 1 mg | Oral | a | Panafcortelone | AS | MP NP |  |  | 100 | 4 | 100 |  |  |
|  |  |  | a | Predsolone | LN | MP NP |  |  | 100 | 4 | 100 |  |  |
|  |  |  | a | Panafcortelone | AS | MP NP |  | P14238 | 200 | 4 | 100 |  |  |
|  |  |  | a | Predsolone | LN | MP NP |  | P14238 | 200 | 4 | 100 |  |  |
|  | Tablet 5 mg | Oral |  | Panafcortelone | AS | MP NP |  |  | 60 | 4 | 60 |  |  |
|  |  |  |  | Solone | IL | MP NP |  |  | 60 | 4 | 60 |  |  |
|  |  |  |  | Panafcortelone | AS | MP NP |  | P14238 | 120 | 4 | 60 |  |  |
|  |  |  |  | Solone | IL | MP NP |  | P14238 | 120 | 4 | 60 |  |  |
|  | Tablet 25 mg | Oral |  | Panafcortelone | AS | MP NP |  |  | 30 | 4 | 30 |  |  |
|  |  |  |  | Solone | IL | MP NP |  |  | 30 | 4 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Prednisone in the form Tablet 1 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Prednisone | Tablet 1 mg | Oral | a | Panafcort | AS | MP NP |  |  | 100 | 4 | 100 |  |  |
|  |  |  | a | Predsone | LN | MP NP |  |  | 100 | 4 | 100 |  |  |
|  |  |  | a | Panafcort | AS | MP NP |  | P14238 | 200 | 4 | 100 |  |  |
|  |  |  | a | Predsone | LN | MP NP |  | P14238 | 200 | 4 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Prednisone in the form Tablet 5 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 5 mg | Oral |  | Panafcort | AS | MP NP |  |  | 60 | 4 | 60 |  |  |
|  |  |  |  | Sone | IL | MP NP |  |  | 60 | 4 | 60 |  |  |
|  |  |  |  | Panafcort | AS | MP NP |  | P14238 | 120 | 4 | 60 |  |  |
|  |  |  |  | Sone | IL | MP NP |  | P14238 | 120 | 4 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Probenecid**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Probenecid | Tablet 500 mg | Oral |  | Pro-Cid | FF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Propantheline**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Propantheline | Tablet containing propantheline bromide 15 mg | Oral |  | Pro-Banthine | RW | MP NP | C6241 C14915 | P6241 | 200 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C6241 C14915 | P14915 | 400 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Propylthiouracil**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Propylthiouracil | Tablet 50 mg | Oral |  | PTU | FF | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Quinagolide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Quinagolide | Tablet 75 micrograms (as hydrochloride) | Oral |  | Norprolac | FP | MP | C5136 C5137 C5357 C5398 C14918 C14959 C14983 C15005 | P5136 P5137 P5357 P5398 | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP | C5136 C5137 C5357 C5398 C14918 C14959 C14983 C15005 | P14918 P14959 P14983 P15005 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Saxagliptin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Saxagliptin | Tablet 2.5 mg (as hydrochloride) | Oral |  | Onglyza | AP | MP | C6346 C6363 C7505 C7541 C14858 C14911 C14954 | P6346 P6363 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C7505 C14858 C14911 C14954 | P6346 P6363 P7505 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C6346 C6363 C7505 C7541 C14858 C14911 C14954 | P14858 P14911 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C7505 C14858 C14911 C14954 | P14858 P14911 P14954 | 56 | 5 | 28 |  |  |
|  | Tablet 5 mg (as hydrochloride) | Oral |  | Onglyza | AP | MP | C6346 C6363 C7505 C7541 C14858 C14911 C14954 | P6346 P6363 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C7505 C14858 C14911 C14954 | P6346 P6363 P7505 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C6346 C6363 C7505 C7541 C14858 C14911 C14954 | P14858 P14911 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C7505 C14858 C14911 C14954 | P14858 P14911 P14954 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Saxagliptin with dapagliflozin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Saxagliptin with dapagliflozin | Tablet containing saxagliptin 5 mg with dapaglifozin 10 mg | Oral |  | Qtern 5/10 | AP | MP | C7524 C7556 C14885 | P7524 P7556 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C7556 C14885 | P7556 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C7524 C7556 C14885 | P14885 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C7556 C14885 | P14885 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Saxagliptin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Saxagliptin with metformin | Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | Oral |  | Kombiglyze XR 2.5/1000 | AP | MP | C6333 C6335 C6344 C7507 C7530 C14888 C14891 C14937 | P6333 P6335 P6344 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6335 C6344 C7530 C14888 C14891 C14937 | P6333 P6335 P6344 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP | C6333 C6335 C6344 C7507 C7530 C14888 C14891 C14937 | P14888 P14891 P14937 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6335 C6344 C7530 C14888 C14891 C14937 | P14888 P14891 P14937 | 112 | 5 | 56 |  |  |
|  | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride | Oral |  | Kombiglyze XR 5/500 | AP | MP | C6333 C6335 C6344 C7507 C7530 C14888 C14891 C14937 | P6333 P6335 P6344 P7507 P7530 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6335 C6344 C7530 C14888 C14891 C14937 | P6333 P6335 P6344 P7530 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C6333 C6335 C6344 C7507 C7530 C14888 C14891 C14937 | P14888 P14891 P14937 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6335 C6344 C7530 C14888 C14891 C14937 | P14888 P14891 P14937 | 56 | 5 | 28 |  |  |
|  | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | Oral |  | Kombiglyze XR 5/1000 | AP | MP | C6333 C6335 C6344 C7507 C7530 C14888 C14891 C14937 | P6333 P6335 P6344 P7507 P7530 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6335 C6344 C7530 C14888 C14891 C14937 | P6333 P6335 P6344 P7530 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | MP | C6333 C6335 C6344 C7507 C7530 C14888 C14891 C14937 | P14888 P14891 P14937 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6335 C6344 C7530 C14888 C14891 C14937 | P14888 P14891 P14937 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Sevelamer**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sevelamer | Tablet containing sevelamer carbonate 800 mg | Oral |  | Sevelamer Apotex | TX | MP NP | C5491 C14984 | P5491 | 180 | 5 | 180 |  |  |
|  |  |  |  | Sevelamer Lupin | GQ | MP NP | C5491 C14984 | P5491 | 180 | 5 | 180 |  |  |
|  |  |  |  | Sevelamer Apotex | TX | MP NP | C5491 C14984 | P14984 | 360 | 5 | 180 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 360 | 5 | 180 |  | C(100) |
|  |  |  |  | Sevelamer Lupin | GQ | MP NP | C5491 C14984 | P14984 | 360 | 5 | 180 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 360 | 5 | 180 |  | C(100) |
|  | Tablet containing sevelamer hydrochloride 800 mg | Oral |  | Renagel | GZ | MP NP | C5491 C14984 | P5491 | 180 | 5 | 180 |  |  |
|  |  |  |  |  |  | MP NP | C5491 C14984 | P14984 | 360 | 5 | 180 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 360 | 5 | 180 |  | C(100) |

1. **Schedule 1, Part 1, entry for Sirolimus**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sirolimus | Oral solution 1 mg per mL, 60 mL | Oral |  | Rapamune | PF | MP |  |  | 1 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 2 | 3 | 1 |  |  |
|  |  |  |  |  |  | MP |  | P5795 P9914 | 2 CN5795 CN9914 | 5 CN5795 CN9914 | 1 |  | C(100) |
|  | Tablet 0.5 mg | Oral |  | Rapamune | PF | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5795 P9914 | 200 CN5795 CN9914 | 5 CN5795 CN9914 | 100 |  | C(100) |
|  | Tablet 1 mg | Oral |  | Rapamune | PF | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5795 P9914 | 200 CN5795 CN9914 | 5 CN5795 CN9914 | 100 |  | C(100) |
|  | Tablet 2 mg | Oral |  | Rapamune | PF | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5795 P9914 | 200 CN5795 CN9914 | 5 CN5795 CN9914 | 100 |  | C(100) |

1. **Schedule 1, Part 1, entry for Sitagliptin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin | Tablet 25 mg | Oral | a | Januvia | XW | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Lupin | GQ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Sandoz Pharma | SZ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin SUN | RA | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitaglo | CR | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Xelevia | XT | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Januvia | XW | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Lupin | GQ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Sandoz Pharma | SZ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin SUN | RA | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitaglo | CR | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Xelevia | XT | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  | Tablet 50 mg | Oral | a | Januvia | XW | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Lupin | GQ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Sandoz Pharma | SZ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin SUN | RA | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitaglo | CR | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Xelevia | XT | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Januvia | XW | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Lupin | GQ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Sandoz Pharma | SZ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin SUN | RA | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitaglo | CR | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Xelevia | XT | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  | Tablet 100 mg | Oral | a | Januvia | XW | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Lupin | GQ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Sandoz Pharma | SZ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin SUN | RA | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitaglo | CR | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Xelevia | XT | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 P7541 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P6346 P6363 P6376 P7505 | 28 | 5 | 28 |  |  |
|  |  |  | a | Januvia | XW | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Lupin | GQ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin Sandoz Pharma | SZ | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin SUN | RA | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitaglo | CR | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  | a | Xelevia | XT | MP | C6346 C6363 C6376 C7505 C7541 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6346 C6363 C6376 C7505 C14858 C14911 C14950 C14954 | P14858 P14911 P14950 P14954 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Sitagliptin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | a | Janumet | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | SITAGLIPTIN/METFORMIN 50/500 SUN | RA | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Velmetia | XT | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Janumet | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | SITAGLIPTIN/METFORMIN 50/500 SUN | RA | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Velmetia | XT | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | a | Janumet | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | SITAGLIPTIN/METFORMIN 50/850 SUN | RA | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Velmetia | XT | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Janumet | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | SITAGLIPTIN/METFORMIN 50/850 SUN | RA | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Velmetia | XT | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | a | Janumet XR | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz XR | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Janumet XR | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz XR | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | a | Janumet | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | SITAGLIPTIN/METFORMIN 50/1000 SUN | RA | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Velmetia | XT | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 56 | 5 | 56 |  |  |
|  |  |  | a | Janumet | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | SITAGLIPTIN/METFORMIN 50/1000 SUN | RA | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  | a | Velmetia | XT | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 112 | 5 | 56 |  |  |
|  | Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | a | Janumet XR | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 28 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz XR | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7507 P7530 | 28 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P6333 P6334 P6344 P6443 P7530 | 28 | 5 | 28 |  |  |
|  |  |  | a | Janumet XR | XW | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 56 | 5 | 28 |  |  |
|  |  |  | a | Sitagliptin/Metformin Sandoz XR | SZ | MP | C6333 C6334 C6344 C6443 C7507 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 56 | 5 | 28 |  |  |
|  |  |  |  |  |  | NP | C6333 C6334 C6344 C6443 C7530 C14888 C14891 C14894 C14933 | P14888 P14891 P14894 P14933 | 56 | 5 | 28 |  |  |

1. **Schedule 1, Part 1, entry for Sodium acid phosphate**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sodium acid phosphate | Tablet, compound effervescent, equivalent to 500 mg phosphorus | Oral |  | PHOSPHATE PHEBRA | FG | MP NP | C5089 C5095 C5114 C5123 C14874 C14921 C14922 C14962 | P5089 P5095 P5114 P5123 | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C5089 C5095 C5114 C5123 C14874 C14921 C14922 C14962 | P14874 P14921 P14922 P14962 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Sodium bicarbonate**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sodium bicarbonate | Capsule 840 mg | Oral |  | Sodibic | AS | MP NP |  |  | 100 | 2 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 200 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Spironolactone in the form Tablet 100 mg**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 100 mg | Oral | a | Aldactone | PF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Spiractin 100 | AF | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Spironolactone Viatris 100 | AL | MP NP |  |  | 100 | 5 | 100 |  |  |
|  |  |  | a | Aldactone | PF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Spiractin 100 | AF | MP NP |  | P14238 | 200 | 5 | 100 |  |  |
|  |  |  | a | Spironolactone Viatris 100 | AL | MP NP |  | P14238 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Sucroferric oxyhydroxide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sucroferric oxyhydroxide | Tablet, chewable, 2.5 g (equivalent to 500 mg iron) | Oral |  | Velphoro | VL | MP NP | C5491 C14872 | P5491 | 90 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP NP | C5491 C14872 | P14872 | 180 | 5 | 90 |  |  |
|  |  |  |  |  |  | MP | C5530 C9762 |  | 180 | 5 | 90 |  | C(100) |

1. **Schedule 1, Part 1, entry for Sulthiame**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sulthiame | Tablet 50 mg | Oral |  | Ospolot | FF | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |
|  | Tablet 200 mg | Oral |  | Ospolot | FF | MP NP |  |  | 200 | 2 | 200 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 200 |  |  |

1. **Schedule 1, Part 1, entry for Tacrolimus**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tacrolimus | Capsule 0.5 mg | Oral | a | Pacrolim | AF | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Pharmacor Tacrolimus 0.5 | CR | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Prograf | LL | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Tacrograf | RW | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Pacrolim | AF | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Pharmacor Tacrolimus 0.5 | CR | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Prograf | LL | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Tacrograf | RW | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Pacrolim | AF | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Pharmacor Tacrolimus 0.5 | CR | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Prograf | LL | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Tacrograf | RW | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  | Capsule 0.5 mg (once daily prolonged release) | Oral |  | ADVAGRAF XL | LQ | MP |  |  | 30 | 3 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 60 | 3 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P5569 P9697 | 60 CN5569 CN9697 | 5 CN5569 CN9697 | 30 |  | C(100) |
|  | Capsule 0.75 mg | Oral |  | Tacrolimus Sandoz | SZ | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  | Capsule 1 mg | Oral | a | Pacrolim | AF | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Pharmacor Tacrolimus 1 | CR | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Prograf | LL | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Tacrograf | RW | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  | a | Pacrolim | AF | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Pharmacor Tacrolimus 1 | CR | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Prograf | LL | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Tacrograf | RW | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  | a | Pacrolim | AF | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Pharmacor Tacrolimus 1 | CR | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Prograf | LL | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Tacrograf | RW | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  | Capsule 1 mg (once daily prolonged release) | Oral |  | ADVAGRAF XL | LQ | MP |  |  | 60 | 3 | 60 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 120 | 3 | 60 |  |  |
|  |  |  |  |  |  | MP |  | P5569 P9697 | 120 CN5569 CN9697 | 5 CN5569 CN9697 | 60 |  | C(100) |
|  | Capsule 2 mg | Oral |  | Tacrolimus Sandoz | SZ | MP |  |  | 100 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 200 | 3 | 100 |  |  |
|  |  |  |  |  |  | MP |  | P5569 P9697 | 200 CN5569 CN9697 | 5 CN5569 CN9697 | 100 |  | C(100) |
|  | Capsule 3 mg (once daily prolonged release) | Oral |  | ADVAGRAF XL | LQ | MP |  |  | 50 | 2 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 100 | 2 | 50 |  |  |
|  |  |  |  |  |  | MP |  | P5569 P9697 | 100 CN5569 CN9697 | 3 CN5569 CN9697 | 50 |  | C(100) |
|  | Capsule 5 mg | Oral | a | Pharmacor Tacrolimus 5 | CR | MP |  |  | 50 | 3 | 50 |  |  |
|  |  |  | a | Prograf | LL | MP |  |  | 50 | 3 | 50 |  |  |
|  |  |  | a | Tacrograf | RW | MP |  |  | 50 | 3 | 50 |  |  |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  |  | 50 | 3 | 50 |  |  |
|  |  |  | a | Pharmacor Tacrolimus 5 | CR | MP |  | P14238 | 100 | 3 | 50 |  |  |
|  |  |  | a | Prograf | LL | MP |  | P14238 | 100 | 3 | 50 |  |  |
|  |  |  | a | Tacrograf | RW | MP |  | P14238 | 100 | 3 | 50 |  |  |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  | P14238 | 100 | 3 | 50 |  |  |
|  |  |  | a | Pharmacor Tacrolimus 5 | CR | MP |  | P5569 P9697 | 100 CN5569 CN9697 | 5 CN5569 CN9697 | 50 |  | C(100) |
|  |  |  | a | Prograf | LL | MP |  | P5569 P9697 | 100 CN5569 CN9697 | 5 CN5569 CN9697 | 50 |  | C(100) |
|  |  |  | a | Tacrograf | RW | MP |  | P5569 P9697 | 100 CN5569 CN9697 | 5 CN5569 CN9697 | 50 |  | C(100) |
|  |  |  | a | Tacrolimus Sandoz | SZ | MP |  | P5569 P9697 | 100 CN5569 CN9697 | 5 CN5569 CN9697 | 50 |  | C(100) |
|  | Capsule 5 mg (once daily prolonged release) | Oral |  | ADVAGRAF XL | LQ | MP |  |  | 30 | 3 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 60 | 3 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P5569 P9697 | 60 CN5569 CN9697 | 5 CN5569 CN9697 | 30 |  | C(100) |

1. **Schedule 1, Part 1, entry for Tamoxifen**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tamoxifen | Tablet 20 mg (as citrate) | Oral | a | Genox 20 | AF | MP NP | C6381 C6421 C14895 C14989 | P6421 | 30 | 5 | 30 |  |  |
|  |  |  | a | Nolvadex-D | AP | MP NP | C6421 C6449 C14895 C14989 | P6421 | 30 | 5 | 30 |  |  |
|  |  |  | a | Genox 20 | AF | MP NP | C6381 C6421 C14895 C14989 | P14989 | 60 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP NP | C6381 C6421 C14895 C14989 | P6381 | 60 | 5 | 60 |  |  |
|  |  |  | a | Nolvadex-D | AP | MP NP | C6421 C6449 C14895 C14989 | P6449 P14989 | 60 | 5 | 30 |  |  |
|  |  |  | a | GenRx Tamoxifen | GX | MP NP | C6381 C14895 | P6381 | 60 | 5 | 60 |  |  |
|  |  |  | a | Tamosin | OX | MP NP | C6381 C14895 | P6381 | 60 | 5 | 60 |  |  |
|  |  |  | a | Tamoxifen Sandoz | SZ | MP NP | C6381 C14895 | P6381 | 60 | 5 | 60 |  |  |
|  |  |  | a | Nolvadex-D | AP | MP NP | C6421 C6449 C14895 C14989 | P14895 | 120 | 5 | 30 |  |  |
|  |  |  | a | Genox 20 | AF | MP NP | C6381 C6421 C14895 C14989 | P14895 | 120 | 5 | 60 |  |  |
|  |  |  | a | GenRx Tamoxifen | GX | MP NP | C6381 C14895 | P14895 | 120 | 5 | 60 |  |  |
|  |  |  | a | Tamosin | OX | MP NP | C6381 C14895 | P14895 | 120 | 5 | 60 |  |  |
|  |  |  | a | Tamoxifen Sandoz | SZ | MP NP | C6381 C14895 | P14895 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Teriparatide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Teriparatide | Injection 250 micrograms per mL, 2.4 mL in multi-dose pre‑filled cartridge | Injection |  | Terrosa | FX | MP | C12270 C12492 C14997 | P12270 P12492 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C12270 C12492 C14997 | P14997 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2 | Transdermal |  | Testogel | HB | MP | C6324 C6910 C6919 C6933 C6934 C14912 C14913 C14955 C14956 C15015 | P6324 P6910 P6919 P6933 P6934 | 1 | 4 | 1 |  |  |
|  |  |  |  |  |  | MP | C6324 C6910 C6919 C6933 C6934 C14912 C14913 C14955 C14956 C15015 | P14912 P14913 P14955 P14956 P15015 | 2 | 4 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses | Transdermal |  | Testavan | IX | MP | C6324 C6910 C6919 C6933 C6934 C14912 C14913 C14955 C14956 C15015 | P6324 P6910 P6919 P6933 P6934 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6324 C6910 C6919 C6933 C6934 C14912 C14913 C14955 C14956 C15015 | P14912 P14913 P14955 P14956 P15015 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Testosterone in the form Transdermal gel 50 mg in 5 g sachet, 30**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Transdermal gel 50 mg in 5 g sachet, 30 | Transdermal |  | Testogel | HB | MP | C6324 C6910 C6919 C6933 C6934 C14912 C14913 C14955 C14956 C15015 | P6324 P6910 P6919 P6933 P6934 | 1 | 5 | 1 |  |  |
|  |  |  |  |  |  | MP | C6324 C6910 C6919 C6933 C6934 C14912 C14913 C14955 C14956 C15015 | P14912 P14913 P14955 P14956 P15015 | 2 | 5 | 1 |  |  |

1. **Schedule 1, Part 1, entry for Tiagabine**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tiagabine | Tablet 5 mg (as hydrochloride) | Oral |  | Gabitril | TB | MP NP | C4928 C14883 | P4928 | 100 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP NP | C4928 C14883 | P14883 | 200 | 5 | 50 |  |  |
|  | Tablet 10 mg (as hydrochloride) | Oral |  | Gabitril | TB | MP NP | C4928 C14883 | P4928 | 100 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP NP | C4928 C14883 | P14883 | 200 | 5 | 50 |  |  |
|  | Tablet 15 mg (as hydrochloride) | Oral |  | Gabitril | TB | MP NP | C4928 C14883 | P4928 | 100 | 5 | 50 |  |  |
|  |  |  |  |  |  | MP NP | C4928 C14883 | P14883 | 200 | 5 | 50 |  |  |

1. **Schedule 1, Part 1, entry for Tobramycin in the form Capsule containing powder for oral inhalation 28 mg (for use in podhaler)**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Tobramycin | Capsule containing powder for oral inhalation 28 mg (for use in podhaler) | Inhalation by mouth |  | TOBI podhaler | GO | MP | C4456 C4513 C15036 | P4456 | 224 | 0 | 224 |  |  |
|  |  |  |  |  |  | MP | C4456 C4513 C15036 | P4513 | 224 | 2 | 224 |  |  |
|  |  |  |  |  |  | MP | C4456 C4513 C15036 | P15036 | 448 | 2 | 224 |  |  |

1. **Schedule 1, Part 1, entry for Tobramycin in the form Solution for inhalation 300 mg in 5 mL**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Solution for inhalation 300 mg in 5 mL | Inhalation | a | Tobi | GO | MP | C5520 C15040 | P5520 | 56 | 2 | 56 |  |  |
|  |  |  | a | TOBRAMYCIN SUN | RA | MP | C5520 C15040 | P5520 | 56 | 2 | 56 |  |  |
|  |  |  | a | Tobramycin WKT | LI | MP | C5520 C15040 | P5520 | 56 | 2 | 56 |  |  |
|  |  |  | a | Tobi | GO | MP | C5520 C15040 | P15040 | 112 | 2 | 56 |  |  |
|  |  |  | a | TOBRAMYCIN SUN | RA | MP | C5520 C15040 | P15040 | 112 | 2 | 56 |  |  |
|  |  |  | a | Tobramycin WKT | LI | MP | C5520 C15040 | P15040 | 112 | 2 | 56 |  |  |

1. **Schedule 1, Part 1, entry for Topiramate**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Topiramate | Capsule 15 mg | Oral |  | Topamax Sprinkle | JC | MP NP | C5173 C14931 | P5173 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C5173 C14931 | P14931 | 120 | 5 | 60 |  |  |
|  | Capsule 25 mg | Oral |  | Topamax Sprinkle | JC | MP NP | C5173 C14931 | P5173 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C5173 C14931 | P14931 | 120 | 5 | 60 |  |  |
|  | Capsule 50 mg | Oral |  | Topamax Sprinkle | JC | MP NP | C5173 C14931 | P5173 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C5173 C14931 | P14931 | 120 | 5 | 60 |  |  |
|  | Tablet 25 mg | Oral | a | APO-Topiramate | TX | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 25 | RW | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Topiramate | TX | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 25 | RW | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  | Tablet 50 mg | Oral | a | APO-Topiramate | TX | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 50 | RW | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Topiramate | TX | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 50 | RW | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  | Tablet 100 mg | Oral | a | APO-Topiramate | TX | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 100 | RW | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5325 C5516 C14901 C14973 | P5325 P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Topiramate | TX | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 100 | RW | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5325 C5516 C14901 C14973 | P14901 P14973 | 120 | 5 | 60 |  |  |
|  | Tablet 200 mg | Oral | a | APO-Topiramate | TX | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 200 | RW | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5516 C14973 | P5516 | 60 | 5 | 60 |  |  |
|  |  |  | a | APO-Topiramate | TX | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Epiramax 200 | RW | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | NOUMED TOPIRAMATE | VO | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | RBX Topiramate | RA | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Tamate | AF | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topamax | JC | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |
|  |  |  | a | Topiramate Sandoz | SZ | MP NP | C5516 C14973 | P14973 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Toremifene**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Toremifene | Tablet 60 mg (as citrate) | Oral |  | Fareston | OX | MP |  |  | 30 | 5 | 30 |  |  |
|  |  |  |  |  |  | MP |  | P14238 | 60 | 5 | 30 |  |  |

1. **Schedule 1, Part 1, entry for Valproic acid**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Valproic acid | Oral liquid containing sodium valproate 200 mg per 5 mL, 300 mL | Oral |  | Epilim Liquid | SW | MP NP |  |  | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 4 | 2 | 1 |  |  |
|  | Oral solution containing sodium valproate 200 mg per 5 mL, 300 mL | Oral |  | Epilim Syrup | SW | MP NP |  |  | 2 | 2 | 1 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 4 | 2 | 1 |  |  |
|  | Tablet, crushable, containing sodium valproate 100 mg | Oral |  | Epilim | SW | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  |  |  |  | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  | Tablet (enteric coated) containing sodium valproate 200 mg | Oral | a | Epilim EC | SW | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Sodium Valproate Sandoz | SZ | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Valprease 200 | RW | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Valpro EC 200 | AF | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Valproate Winthrop EC 200 | WA | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Epilim EC | SW | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Sodium Valproate Sandoz | SZ | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Valprease 200 | RW | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Valpro EC 200 | AF | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Valproate Winthrop EC 200 | WA | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  | Tablet (enteric coated) containing sodium valproate 500 mg | Oral | a | Epilim EC | SW | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Sodium Valproate Sandoz | SZ | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Valprease 500 | RW | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Valpro EC 500 | AF | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Valproate Winthrop EC 500 | WA | MP NP |  |  | 200 | 2 | 100 |  |  |
|  |  |  | a | Epilim EC | SW | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Sodium Valproate Sandoz | SZ | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Valprease 500 | RW | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Valpro EC 500 | AF | MP NP |  | P14238 | 400 | 2 | 100 |  |  |
|  |  |  | a | Valproate Winthrop EC 500 | WA | MP NP |  | P14238 | 400 | 2 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Vigabatrin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Vigabatrin | Oral powder, sachet 500 mg | Oral |  | Sabril | SW | MP NP | C4929 C14903 | P4929 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C4929 C14903 | P14903 | 120 | 5 | 60 |  |  |
|  | Tablet 500 mg | Oral |  | Sabril | SW | MP NP | C4929 C14903 | P4929 | 100 | 5 | 100 |  |  |
|  |  |  |  |  |  | MP NP | C4929 C14903 | P14903 | 200 | 5 | 100 |  |  |

1. **Schedule 1, Part 1, entry for Vildagliptin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Vildagliptin | Tablet 50 mg | Oral |  | Galvus | NV | MP NP | C6346 C6363 C6376 C14978 C14999 C15000 | P6346 P6363 P6376 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C6346 C6363 C6376 C14978 C14999 C15000 | P14978 P14999 P15000 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Vildagliptin with metformin**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride | Oral |  | Galvumet 50/500 | NV | MP NP | C6333 C6344 C6357 C6443 C14887 C14888 C14894 | P6333 P6344 P6357 P6443 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C6333 C6344 C6357 C6443 C14887 C14888 C14894 | P14887 P14888 P14894 | 120 | 5 | 60 |  |  |
|  | Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride | Oral |  | Galvumet 50/850 | NV | MP NP | C6333 C6344 C6357 C6443 C14887 C14888 C14894 | P6333 P6344 P6357 P6443 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C6333 C6344 C6357 C6443 C14887 C14888 C14894 | P14887 P14888 P14894 | 120 | 5 | 60 |  |  |
|  | Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride | Oral |  | Galvumet 50/1000 | NV | MP NP | C6333 C6344 C6357 C6443 C14887 C14888 C14894 | P6333 P6344 P6357 P6443 | 60 | 5 | 60 |  |  |
|  |  |  |  |  |  | MP NP | C6333 C6344 C6357 C6443 C14887 C14888 C14894 | P14887 P14888 P14894 | 120 | 5 | 60 |  |  |

1. **Schedule 1, Part 1, entry for Zonisamide**

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Zonisamide | Capsule 25 mg | Oral |  | Zonegran | GH | MP NP | C4928 C14883 | P4928 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C4928 C14883 | P14883 | 112 | 5 | 56 |  |  |
|  | Capsule 50 mg | Oral |  | Zonegran | GH | MP NP | C4928 C14883 | P4928 | 56 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C4928 C14883 | P14883 | 112 | 5 | 56 |  |  |
|  | Capsule 100 mg | Oral |  | Zonegran | GH | MP NP | C4928 C14883 | P4928 | 112 | 5 | 56 |  |  |
|  |  |  |  |  |  | MP NP | C4928 C14883 | P14883 | 224 | 5 | 56 |  |  |

1. **Schedule 4, Part 1, after entry for Acamprosate**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Acarbose |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Alendronic acid with colecalciferol**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6306”:* **P6306**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6307”:* **P6307**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6315”:* **P6315**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C6319”:* **P6319**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C6320”:* **P6320**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C6325”:* **P6325**
8. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14898 | P14898 |  | Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14898 |
|  | C14993 | P14993 |  | Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 14993 |
|  | C15011 | P15011 |  | Osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be aged 70 years or older. Patient must have a Bone Mineral Density (BMD) T-score of -2.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 15011 |
|  | C15024 | P15024 |  | Corticosteroid-induced osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 15024 |
|  | C15032 | P15032 |  | Corticosteroid-induced osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must currently be on long-term (at least 3 months), high-dose (at least 7.5 mg per day prednisolone or equivalent) corticosteroid therapy; AND Patient must have a Bone Mineral Density (BMD) T-score of -1.5 or less; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The duration and dose of corticosteroid therapy together with the date, site (femoral neck or lumbar spine) and score of the qualifying BMD measurement must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 15032 |
|  | C15035 | P15035 |  | Established osteoporosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition. The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated. A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body. | Compliance with Authority Required procedures - Streamlined Authority Code 15035 |

1. **Schedule 4, Part 1, entry for Alogliptin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4349”:* **P4349**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14862 | P14862 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with alogliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14862 |

1. **Schedule 4, Part 1, entry for Alogliptin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4423”:* **P4423**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C4427”:* **P4427**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14876 | P14876 |  | Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and alogliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14876 |

1. **Schedule 4, Part 1, entry for Anastrozole**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5464”:* **P5464**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14943 | P14943 |  | Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive. |  |

1. **Schedule 4, Part 1, entry for Bromocriptine**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14914 | P14914 |  | Acromegaly The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  | C14981 | P14981 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution. |  |
|  | C15017 | P15017 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had radiotherapy for this condition with incomplete resolution. |  |
|  | C15028 | P15028 |  | Parkinson disease The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  | C15043 | P15043 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated. |  |
|  | C15044 | P15044 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated. |  |

1. **Schedule 4, Part 1, entry for Cabergoline**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14918 | P14918 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated. |  |
|  | C14959 | P14959 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated. |  |
|  | C14983 | P14983 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had radiotherapy for this condition with incomplete resolution. |  |
|  | C15005 | P15005 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution. |  |

1. **Schedule 4, Part 1, after entry for Captopril**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Carbamazepine |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Carbimazole |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Ciclosporin**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Corifollitropin alfa**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cortisone |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Cyproterone**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  |  | P14868 | CN14868 | Moderate to severe androgenisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be indicated by acne alone, as this is not a sufficient indication of androgenisation. Patient must be female. Patient must not be pregnant. | Compliance with Authority Required procedures - Streamlined Authority Code 14868 |

1. **Schedule 4, Part 1, entry for Dapagliflozin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4991”:* **P4991**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5629”:* **P5629**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C7495”:* **P7495**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C7506”:* **P7506**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7528”:* **P7528**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C12477”:* **P12477**
8. *insert in the column headed “Purposes Code” for the Circumstances Code “C13230”:* **P13230**
9. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14859 | P14859 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14859 |
|  | C14905 | P14905 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14905 |
|  | C14949 | P14949 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14949 |
|  | C14974 | P14974 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14974 |
|  | C14976 | P14976 |  | Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be symptomatic with NYHA classes II, III or IV; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 14976 |

1. **Schedule 4, Part 1, entry for Dapagliflozin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5631”:* **P5631**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5657”:* **P5657**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5739”:* **P5739**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C5798”:* **P5798**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7492”:* **P7492**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C7498”:* **P7498**
8. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14878 | P14878 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 14878 |
|  | C14881 | P14881 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14881 |
|  | C14924 | P14924 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14924 |
|  | C14987 | P14987 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and dapagliflozin. | Compliance with Authority Required procedures - Streamlined Authority Code 14987 |

1. **Schedule 4, Part 1, entry for Desmopressin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5226”:* **P5226**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5412”:* **P5412**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14842 | P14842 |  | Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated No more than twice the maximum quantity will be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 14842 |
|  | C14945 | P14945 |  | Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm. No increase in the maximum quantity or number of units may be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 14945 |
|  | C14972 | P14972 |  | Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be refractory to an enuresis alarm. No more than twice the maximum quantity will be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 14972 |
|  | C15012 | P15012 |  | Cranial diabetes insipidus The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures - Streamlined Authority Code 15012 |
|  | C15025 | P15025 |  | Primary nocturnal enuresis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be 6 years of age or older. Patient must be one in whom an enuresis alarm is contraindicated. The reason that an enuresis alarm is contraindicated must be documented in the patient's medical records when treatment is initiated No increase in the maximum quantity or number of units may be authorised. | Compliance with Authority Required procedures - Streamlined Authority Code 15025 |

1. **Schedule 4, Part 1, entry for Dexamethasone**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Dutasteride**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6202”:* **P6202**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C15018 | P15018 |  | Benign prostatic hyperplasia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia; AND The treatment must be in combination with an alpha-antagonist. | Compliance with Authority Required procedures - Streamlined Authority Code 15018 |

1. **Schedule 4, Part 1, entry for Dutasteride with tamsulosin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6189”:* **P6189**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C15004 | P15004 |  | Benign prostatic hyperplasia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have lower urinary tract symptoms; AND Patient must have moderate to severe benign prostatic hyperplasia. | Compliance with Authority Required procedures - Streamlined Authority Code 15004 |

1. **Schedule 4, Part 1, entry for Empagliflozin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4991”:* **P4991**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5629”:* **P5629**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C7495”:* **P7495**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C7506”:* **P7506**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7528”:* **P7528**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C12477”:* **P12477**
8. *insert in the column headed “Purposes Code” for the Circumstances Code “C14471”:* **P14471**
9. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14859 | P14859 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14859 |
|  | C14905 | P14905 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of triple oral therapy with a gliptin and an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14905 |
|  | C14949 | P14949 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14949 |
|  | C14974 | P14974 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14974 |
|  | C14976 | P14976 |  | Chronic heart failure The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be symptomatic with NYHA classes II, III or IV; AND Patient must have a documented left ventricular ejection fraction (LVEF) of less than or equal to 40%; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include a beta-blocker, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an ACE inhibitor, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin II antagonist, unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; OR The treatment must be an add-on therapy to optimal standard chronic heart failure treatment, which must include an angiotensin receptor with neprilysin inhibitor combination therapy unless contraindicated according to the TGA-approved Product Information or cannot be tolerated; AND Patient must not be receiving treatment with another sodium-glucose co-transporter 2 (SGLT2) inhibitor. | Compliance with Authority Required procedures - Streamlined Authority Code 14976 |

1. **Schedule 4, Part 1, entry for Empagliflozin with linagliptin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C7524”:* **P7524**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C7556”:* **P7556**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14885 | P14885 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14885 |

1. **Schedule 4, Part 1, entry for Empagliflozin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5657”:* **P5657**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5798”:* **P5798**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5953”:* **P5953**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C5966”:* **P5966**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7492”:* **P7492**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C7498”:* **P7498**
8. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14878 | P14878 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 14878 |
|  | C14881 | P14881 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14881 |
|  | C14924 | P14924 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a dipeptidyl peptidase 4 inhibitor (gliptin); AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14924 |
|  | C14925 | P14925 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and empagliflozin. | Compliance with Authority Required procedures - Streamlined Authority Code 14925 |

1. **Schedule 4, Part 1, entry for Eprosartan**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  |  | P14841 | CN14841 | Drug interactions expected to occur with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures |
|  |  | P14969 | CN14969 | Adverse effects occurring with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures |
|  |  | P14970 | CN14970 | Drug interactions occurring with all of the base-priced drugs The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures |
|  |  | P15009 | CN15009 | Transfer to a base-priced drug would cause patient confusion resulting in problems with compliance The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures |

1. **Schedule 4, Part 1, after entry for Essential amino acids formula with vitamins and minerals**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Estradiol |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Estradiol and estradiol with dydrogesterone |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Estradiol and estradiol with norethisterone |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Estradiol with norethisterone |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Estriol |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Etanercept**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ethosuximide |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Everolimus**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Exemestane**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4796”:* **P4796**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5522”:* **P5522**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14992 | P14992 |  | Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive. |  |
|  | C15031 | P15031 |  | Metastatic (Stage IV) breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive; AND The condition must be human epidermal growth factor receptor 2 (HER2) negative; AND Patient must be receiving PBS-subsidised everolimus concomitantly for this condition. Patient must not be pre-menopausal. |  |

1. **Schedule 4, Part 1, after entry for Glecaprevir with pibrentasvir**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Glibenclamide |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Gliclazide |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Glimepiride |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
| Glipizide |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Hydrocortisone**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Ketoprofen**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Labetalol |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Lacosamide**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14853 | P14853 |  | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Must be treated by a neurologist; OR Must be treated by a paediatrician; AND Must be treated by an eligible practitioner type who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion. The condition must have failed to be controlled satisfactorily by at least two anti-epileptic drugs prior to when the drug is/was first commenced; AND The treatment must have been in combination with at least one PBS-subsidised anti-epileptic drug at the time the drug was first commenced. | Compliance with Authority Required procedures - Streamlined Authority Code 14853 |
|  | C14857 | P14857 |  | Intractable partial epileptic seizures Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14857 |

1. **Schedule 4, Part 1, entry for Lamotrigine**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C11081”:* **P11081**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14855 | P14855 |  | Epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR Patient must be a woman of childbearing potential. | Compliance with Authority Required procedures - Streamlined Authority Code 14855 |

1. **Schedule 4, Part 1, entry for Lanthanum**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5491”:* **P5491**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14872 | P14872 |  | Hyperphosphataemia Maintenance following initiation and stabilisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 14872 |

1. **Schedule 4, Part 1, entry for Leflunomide**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C13753”:* **P13753**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C13771”:* **P13771**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14941 | P14941 |  | Severe active psoriatic arthritis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND The treatment must be initiated by a physician. |  |
|  | C14942 | P14942 |  | Severe active rheumatoid arthritis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received, and failed to achieve an adequate response to, one or more disease modifying anti-rheumatic drugs including methotrexate; OR Patient must be clinically inappropriate for treatment with one or more disease modifying anti-rheumatic drugs including methotrexate; AND The treatment must be initiated by a physician. |  |

1. **Schedule 4, Part 1, entry for Letrozole**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5464”:* **P5464**
3. *insert in numerical order after existing text:*

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| --- | --- | --- | --- | --- | --- |
|  | C14943 | P14943 |  | Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive. |  |

1. **Schedule 4, Part 1, entry for Levetiracetam**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C11077”:* **P11077**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C11116”:* **P11116**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14964 | P14964 |  | Partial epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR Patient must be a woman of childbearing potential; AND The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 14964 |
|  | C14988 | P14988 |  | Partial epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; OR Patient must be a woman of childbearing potential; AND Patient must be unable to take a solid dose form of levetiracetam; AND The treatment must not be given concomitantly with brivaracetam, except for cross titration. | Compliance with Authority Required procedures - Streamlined Authority Code 14988 |

1. **Schedule 4, Part 1, entry for Linagliptin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6346”:* **P6346**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6363”:* **P6363**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6376”:* **P6376**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C7505”:* **P7505**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7541”:* **P7541**
7. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14858 | P14858 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14858 |
|  | C14911 | P14911 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14911 |
|  | C14950 | P14950 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14950 |
|  | C14954 | P14954 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14954 |

1. **Schedule 4, Part 1, entry for Linagliptin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6333”:* **P6333**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6336”:* **P6336**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6344”:* **P6344**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C6443”:* **P6443**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7507”:* **P7507**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C7530”:* **P7530**
8. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14888 | P14888 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 14888 |
|  | C14891 | P14891 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14891 |
|  | C14894 | P14894 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14894 |
|  | C14935 | P14935 |  | Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and linagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14935 |

1. **Schedule 4, Part 1, entry for Liothyronine**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6382”:* **P6382**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6410”:* **P6410**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6475”:* **P6475**
5. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14843 | P14843 |  | Thyroid cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures - Streamlined Authority Code 14843 |
|  | C14844 | P14844 |  | Hypothyroidism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be for replacement therapy; AND Patient must have documented intolerance to levothyroxine sodium; OR Patient must have documented resistance to levothyroxine sodium. | Compliance with Authority Required procedures - Streamlined Authority Code 14844 |
|  | C15038 | P15038 |  | Hypothyroidism The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be severe hypothyroidism; AND The treatment must be for initiation of therapy only. | Compliance with Authority Required procedures - Streamlined Authority Code 15038 |

1. **Schedule 4, Part 1, entry for Medroxyprogesterone**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5649”:* **P5649**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5731”:* **P5731**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5791”:* **P5791**
5. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  | C14965 | P14965 |  | Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive. |  |
|  | C14990 | P14990 |  | Endometrial cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  | C15007 | P15007 |  | Advanced breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive. |  |
|  |  | P15030 |  | Endometriosis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Mesna**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Metformin |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Methadone**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Methenamine |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Methotrexate**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Minoxidil**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5177”:* **P5177**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14994 | P14994 |  | Severe refractory hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be initiated by a consultant physician. |  |

1. **Schedule 4, Part 1, entry for Mycophenolic acid**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Nivolumab with relatlimab**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Norethisterone |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Olmesartan with amlodipine**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14839 | P14839 |  | Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with an angiotensin II antagonist; OR The condition must be inadequately controlled with a dihydropyridine calcium channel blocker. |  |

1. **Schedule 4, Part 1, entry for Olmesartan with amlodipine and hydrochlorothiazide**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14837 | P14837 |  | Hypertension The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must not be for the initiation of anti-hypertensive therapy; AND The condition must be inadequately controlled with concomitant treatment with two of the following: an angiotensin II antagonist, a dihydropyridine calcium channel blocker or a thiazide diuretic. |  |

1. **Schedule 4, Part 1, entry for Oxcarbazepine**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5183”:* **P5183**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14932 | P14932 |  | Seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have partial epileptic seizures; OR Patient must have primary generalised tonic-clonic seizures; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 14932 |

1. **Schedule 4, Part 1, entry for Oxybutynin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6241”:* **P6241**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6243”:* **P6243**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14915 | P14915 |  | Detrusor overactivity The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |
|  | C15006 | P15006 |  | Detrusor overactivity The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be unable to tolerate oral oxybutynin; OR Patient must be unable to swallow oral oxybutynin. |  |

1. **Schedule 4, Part 1, entry for Perampanel**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14847 | P14847 |  | Idiopathic generalised epilepsy with primary generalised tonic-clonic seizures Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition. Patient must be aged 12 years or older. | Compliance with Authority Required procedures - Streamlined Authority Code 14847 |
|  | C14852 | P14852 |  | Intractable partial epileptic seizures Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously been issued with an authority prescription for this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14852 |

1. **Schedule 4, Part 1, entry for Phenoxymethylpenicillin**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14947 |  | Recurrent streptococcal infections (including rheumatic fever) The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be for prophylaxis. |  |

1. **Schedule 4, Part 1, after entry for Phenylalanine with carbohydrate**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Phenytoin |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Pioglitazone**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4363”:* **P4363**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C4364”:* **P4364**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C4388”:* **P4388**
5. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C15001 | P15001 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have a contraindication to a combination of metformin and a sulfonylurea; OR Patient must not have tolerated a combination of metformin and a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15001 |
|  | C15002 | P15002 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15002 |
|  | C15014 | P15014 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with maximally tolerated doses of metformin and a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15014 |

1. **Schedule 4, Part 1, after entry for Piroxicam**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pizotifen |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Prednisolone**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Prednisolone with phenylephrine**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Prednisone |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Pregabalin**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Probenecid |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Propantheline**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6241”:* **P6241**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14915 | P14915 |  | Detrusor overactivity The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Propranolol**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Propylthiouracil |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Quinagolide**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5136”:* **P5136**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5137”:* **P5137**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5357”:* **P5357**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C5398”:* **P5398**
6. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14918 | P14918 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom surgery is not indicated. |  |
|  | C14959 | P14959 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must be one in whom radiotherapy is not indicated. |  |
|  | C14983 | P14983 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had radiotherapy for this condition with incomplete resolution. |  |
|  | C15005 | P15005 |  | Pathological hyperprolactinaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have had surgery for this condition with incomplete resolution. |  |

1. **Schedule 4, Part 1, entry for Saxagliptin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6346”:* **P6346**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6363”:* **P6363**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C7505”:* **P7505**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C7541”:* **P7541**
6. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14858 | P14858 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14858 |
|  | C14911 | P14911 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14911 |
|  | C14954 | P14954 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14954 |

1. **Schedule 4, Part 1, entry for Saxagliptin with dapagliflozin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C7524”:* **P7524**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C7556”:* **P7556**
4. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14885 | P14885 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14885 |

1. **Schedule 4, Part 1, entry for Saxagliptin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6333”:* **P6333**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6335”:* **P6335**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6344”:* **P6344**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C7507”:* **P7507**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7530”:* **P7530**
7. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14888 | P14888 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 14888 |
|  | C14891 | P14891 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14891 |
|  | C14937 | P14937 |  | Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and saxagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14937 |

1. **Schedule 4, Part 1, entry for Sevelamer**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5491”:* **P5491**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14984 | P14984 |  | Hyperphosphataemia Maintenance following initiation and stabilisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 14984 |

1. **Schedule 4, Part 1, entry for Sirolimus**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Sitagliptin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6346”:* **P6346**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6363”:* **P6363**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6376”:* **P6376**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C7505”:* **P7505**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7541”:* **P7541**
7. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14858 | P14858 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14858 |
|  | C14911 | P14911 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14911 |
|  | C14950 | P14950 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14950 |
|  | C14954 | P14954 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14954 |

1. **Schedule 4, Part 1, entry for Sitagliptin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6333”:* **P6333**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6334”:* **P6334**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6344”:* **P6344**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C6443”:* **P6443**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C7507”:* **P7507**
7. *insert in the column headed “Purposes Code” for the Circumstances Code “C7530”:* **P7530**
8. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14888 | P14888 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 14888 |
|  | C14891 | P14891 |  | Diabetes mellitus type 2 Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sodium-glucose co-transporter 2 (SGLT2) inhibitor; AND Patient must have previously received a PBS-subsidised regimen of oral diabetic medicines which included a sodium-glucose co-transporter 2 (SGLT2) inhibitor, metformin and a gliptin for this condition. | Compliance with Authority Required procedures - Streamlined Authority Code 14891 |
|  | C14894 | P14894 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14894 |
|  | C14933 | P14933 |  | Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and sitagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14933 |

1. **Schedule 4, Part 1, entry for Sodium acid phosphate**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5089”:* **P5089**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5095”:* **P5095**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5114”:* **P5114**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C5123”:* **P5123**
6. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14874 | P14874 |  | Hypophosphataemic rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures - Streamlined Authority Code 14874 |
|  | C14921 | P14921 |  | Familial hypophosphataemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures - Streamlined Authority Code 14921 |
|  | C14922 | P14922 |  | Hypercalcaemia The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures - Streamlined Authority Code 14922 |
|  | C14962 | P14962 |  | Vitamin D-resistant rickets The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. | Compliance with Authority Required procedures - Streamlined Authority Code 14962 |

1. **Schedule 4, Part 1, after entry for Sodium acid phosphate**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sodium bicarbonate |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Sucroferric oxyhydroxide**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5491”:* **P5491**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14872 | P14872 |  | Hyperphosphataemia Maintenance following initiation and stabilisation The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must not be adequately controlled by calcium; AND Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy; AND The treatment must not be used in combination with any other non-calcium phosphate binding agents. Patient must be undergoing dialysis for chronic kidney disease. | Compliance with Authority Required procedures - Streamlined Authority Code 14872 |

1. **Schedule 4, Part 1, after entry for Sulfasalazine**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sulthiame |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Tacrolimus**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Tamoxifen**

*insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14895 | P14895 |  | Breast cancer The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must be hormone receptor positive. |  |
|  | C14989 | P14989 |  | Reduction of breast cancer risk The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have a moderate or high risk of developing breast cancer; AND The treatment must not exceed a dose of 20 mg per day; AND The treatment must not exceed a lifetime maximum of 5 years for this condition. |  |

1. **Schedule 4, Part 1, entry for Teriparatide**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C12270”:* **P12270**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C12492”:* **P12492**
4. *insert in numerical order after existing text:*

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| --- | --- | --- | --- | --- | --- |
|  | C14997 | P14997 |  | Severe established osteoporosis Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously been issued with an authority prescription for this drug; AND The treatment must not exceed a lifetime maximum of 18 months therapy. Must be treated by a specialist; OR Must be treated by a consultant physician. | Compliance with Authority Required procedures - Streamlined Authority Code 14997 |

1. **Schedule 4, Part 1, entry for Testosterone**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6324”:* **P6324**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6910”:* **P6910**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6919”:* **P6919**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C6933”:* **P6933**
6. *insert in the column headed “Purposes Code” for the Circumstances Code “C6934”:* **P6934**
7. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14912 | P14912 |  | Androgen deficiency The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must not have an established pituitary or testicular disorder; AND The condition must not be due to age, obesity, cardiovascular diseases, infertility or drugs. Patient must be aged 40 years or older. Must be treated by a specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. Androgen deficiency is defined as: (i) testosterone level of less than 6 nmol per litre; OR (ii) testosterone level between 6 and 15 nmol per litre with high luteinising hormone (LH) (greater than 1.5 times the upper limit of the eugonodal reference range for young men, or greater than 14 IU per litre, whichever is higher). Androgen deficiency must be confirmed by at least two morning blood samples taken on different mornings. The dates and levels of the qualifying testosterone and LH measurements must be, or must have been provided in the authority application when treatment with this drug is or was initiated. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
|  | C14913 | P14913 |  | Micropenis The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
|  | C14955 | P14955 |  | Pubertal induction The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
|  | C14956 | P14956 |  | Constitutional delay of growth or puberty The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. Patient must be under 18 years of age. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |
|  | C15015 | P15015 |  | Androgen deficiency The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have an established pituitary or testicular disorder. Must be treated by a specialist general paediatrician, specialist paediatric endocrinologist, specialist urologist, specialist endocrinologist or a Fellow of the Australasian Chapter of Sexual Health Medicine; or in consultation with one of these specialists; or have an appointment to be assessed by one of these specialists. The name of the specialist must be included in the authority application. | Compliance with Authority Required procedures |

1. **Schedule 4, Part 1, entry for Tiagabine**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4928”:* **P4928**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14883 | P14883 |  | Partial epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 14883 |

1. **Schedule 4, Part 1, entry for Tobramycin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5520”:* **P5520**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C15036 | P15036 |  | Proven Pseudomonas aeruginosa infection Continuing treatment The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have cystic fibrosis; AND Patient must have previously been issued with an authority prescription for tobramycin inhalation capsules; AND Patient must have demonstrated ability to tolerate the dry powder formulation following the initial 4-week treatment period, as agreed by the patient, the patient's family (in the case of paediatric patients) and the treating physician(s). Patient must be 6 years of age or older. | Compliance with Authority Required procedures - Streamlined Authority Code 15036 |
|  | C15040 | P15040 |  | Proven Pseudomonas aeruginosa infection The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have cystic fibrosis; AND The treatment must be for management. | Compliance with Authority Required procedures - Streamlined Authority Code 15040 |

1. **Schedule 4, Part 1, entry for Topiramate**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C5173”:* **P5173**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C5325”:* **P5325**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C5516”:* **P5516**
5. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14901 | P14901 |  | Migraine The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be for prophylaxis; AND Patient must have experienced an average of 3 or more migraines per month over a period of at least 6 months; AND Patient must have a contraindication to beta-blockers, as described in the relevant TGA-approved Product Information; OR Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with a beta-blocker; AND Patient must have a contraindication to pizotifen because the weight gain associated with this drug poses an unacceptable risk; OR Patient must have experienced intolerance of a severity necessitating permanent withdrawal during treatment with pizotifen. Details of the contraindication and/or intolerance(s) must be documented in the patient's medical records when treatment is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 14901 |
|  | C14931 | P14931 |  | Seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have partial epileptic seizures; OR Patient must have primary generalised tonic-clonic seizures; OR Patient must have seizures of the Lennox-Gastaut syndrome; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs; AND Patient must be unable to take a solid dose form of topiramate. | Compliance with Authority Required procedures - Streamlined Authority Code 14931 |
|  | C14973 | P14973 |  | Seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have partial epileptic seizures; OR Patient must have primary generalised tonic-clonic seizures; OR Patient must have seizures of the Lennox-Gastaut syndrome; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 14973 |

1. **Schedule 4, Part 1, after entry for Topiramate**

*insert:*

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| --- | --- | --- | --- | --- | --- |
| Toremifene |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, after entry for Valine with carbohydrate**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Valproic acid |  | P14238 |  | The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient. |  |

1. **Schedule 4, Part 1, entry for Vigabatrin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4929”:* **P4929**
3. *insert in numerical order after existing text:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C14903 | P14903 |  | Epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 14903 |

1. **Schedule 4, Part 1, entry for Vildagliptin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6346”:* **P6346**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6363”:* **P6363**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6376”:* **P6376**
5. *insert in numerical order after existing text:*

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| --- | --- | --- | --- | --- | --- |
|  | C14978 | P14978 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14978 |
|  | C14999 | P14999 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with metformin; OR The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% despite treatment with either metformin or a sulfonylurea; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period despite treatment with either metformin or a sulfonylurea. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this drug. | Compliance with Authority Required procedures - Streamlined Authority Code 14999 |
|  | C15000 | P15000 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 15000 |

1. **Schedule 4, Part 1, entry for Vildagliptin with metformin**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C6333”:* **P6333**
3. *insert in the column headed “Purposes Code” for the Circumstances Code “C6344”:* **P6344**
4. *insert in the column headed “Purposes Code” for the Circumstances Code “C6357”:* **P6357**
5. *insert in the column headed “Purposes Code” for the Circumstances Code “C6443”:* **P6443**
6. *insert in numerical order after existing text:*

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| --- | --- | --- | --- | --- | --- |
|  | C14887 | P14887 |  | Diabetes mellitus type 2 Continuing The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND Patient must have previously received and been stabilised on a PBS-subsidised regimen of oral diabetic medicines which includes metformin and vildagliptin. | Compliance with Authority Required procedures - Streamlined Authority Code 14887 |
|  | C14888 | P14888 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with a sulfonylurea; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with optimal doses of dual oral therapy; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with optimal doses of dual oral therapy. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. A patient whose diabetes was previously demonstrated unable to be controlled with metformin or a sulfonylurea does not need to requalify on this criterion before being eligible for PBS-subsidised treatment with this fixed dose combination. | Compliance with Authority Required procedures - Streamlined Authority Code 14888 |
|  | C14894 | P14894 |  | Diabetes mellitus type 2 The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The treatment must be in combination with insulin; AND Patient must have, or have had, a HbA1c measurement greater than 7% prior to the initiation of a dipeptidyl peptidase 4 inhibitor (gliptin), a thiazolidinedione (glitazone), a glucagon-like peptide-1 or a sodium-glucose co-transporter 2 (SGLT2) inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated; OR Patient must have, or have had, where HbA1c measurement is clinically inappropriate, blood glucose levels greater than 10 mmol per L in more than 20% of tests over a 2 week period prior to initiation with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor despite treatment with insulin and oral antidiabetic agents, or insulin alone where metformin is contraindicated. The date and level of the qualifying HbA1c measurement must be, or must have been, documented in the patient's medical records at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor is initiated. The HbA1c must be no more than 4 months old at the time treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor was initiated. Blood glucose monitoring may be used as an alternative assessment to HbA1c levels in the following circumstances: (a) A clinical condition with reduced red blood cell survival, including haemolytic anaemias and haemoglobinopathies; and/or (b) Had red cell transfusion within the previous 3 months. The results of the blood glucose monitoring, which must be no more than 4 months old at the time of initiation of treatment with a gliptin, a glitazone, a glucagon-like peptide-1 or an SGLT2 inhibitor, must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14894 |

1. **Schedule 4, Part 1, entry for Zonisamide**
2. *insert in the column headed “Purposes Code” for the Circumstances Code “C4928”:* **P4928**
3. *insert in numerical order after existing text:*

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|  | C14883 | P14883 |  | Partial epileptic seizures The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient; AND The condition must have failed to be controlled satisfactorily by other anti-epileptic drugs. | Compliance with Authority Required procedures - Streamlined Authority Code 14883 |