

PB 138 of 2024

National Health (Listing of Pharmaceutical Benefits) Amendment (January Update) Instrument 2024

National Health Act 1953

I, EDEN SIMON, Assistant Secretary (Acting), 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 19 December 2024

**EDEN SIMON**
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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*National Health (Listing of Pharmaceutical Benefits) Instrument 2024 (PB 26 of 2024)* 2

1. Name

(1) This instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment (January Update) Instrument 2024*.

(2) This Instrument may also be cited as PB 138 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 January 2025* | *1 January 2025* |

Note: This table relates only to the provisions of this instrument as originally made.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.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

*National Health (Listing of Pharmaceutical Benefits) Instrument 2024 (PB 26 of 2024)*

[1] Schedule 1, Part 1, entries for Abacavir with lamivudine

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Abacavir with lamivudine | Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg | Oral | Abacavir/Lamivudine Mylan | AF | MP NP | C4527 C4528 |  | 60 | 5 |  | 30 |  | D(100) |

[2] Schedule 1, Part 1, after entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen [Brand: Humira; Maximum Quantity: 6; Number of Repeats: 0]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C11713 C15473 | P11713 P15473 | 2 | 0 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C12120 C14061 C14063 C14064 C14107 C14136 | See Note 3 | See Note 3 | See Note 3 |  | 2 |  | C(100) |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 | 2 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C9064 C9386 C11861 C12174 C12194 C13599 C13650 C13681 C13694 C14483 C14486 C14488 C14496 C14498 C14568 C14590 C14655 C14662 C14670 C14672 C14673 | P9064 P9386 P11861 P12174 P12194 P13599 P13650 P13681 P13694 P14483 P14486 P14488 P14496 P14498 P14568 P14590 P14655 P14662 P14670 P14672 P14673 | 2 | 3 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C11107 C12155 C12212 C13556 C13612 C14377 C14378 | P11107 P12155 P12212 P13556 P13612 P14377 P14378 | 2 | 4 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C11523 C11524 C11579 C11604 C11606 C11631 C11635 C11704 C11711 C11717 C11718 C11767 C11853 C11865 C11867 C11903 C11906 C11966 C12122 C12123 C12148 C12156 C12157 C12158 C12189 C12190 C12214 C12228 C12240 C14493 C14499 C14507 C14567 C14656 C14683 C14701 C14713 C14730 C15445 C15446 C15450 | P11523 P11524 P11579 P11604 P11606 P11631 P11635 P11704 P11711 P11717 P11718 P11767 P11853 P11865 P11867 P11903 P11906 P11966 P12122 P12123 P12148 P12156 P12157 P12158 P12189 P12190 P12214 P12228 P12240 P14493 P14499 P14507 P14567 P14656 P14683 P14701 P14713 P14730 P15445 P15446 P15450 | 2 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C15474 C15489 | P15474 P15489 | 2 | 6 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C15788 | P15788 | 4 | 2 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C11529 C15777 C15796 | P11529 P15777 P15796 | 4 | 5 |  | 2 |  |  |
| Adalimumab | Injection 40 mg in 0.4 mL pre-filled pen | Injection | Hyrimoz | SZ | MP | C9715 C11709 C11715 C11716 C11759 C11761 C11852 C11854 C11855 C12098 C12101 C12147 C13602 C13609 C15764 C15765 C15795 | P9715 P11709 P11715 P11716 P11759 P11761 P11852 P11854 P11855 P12098 P12101 P12147 P13602 P13609 P15764 P15765 P15795 | 6 | 0 |  | 2 |  |  |

[3] Schedule 1, Part 1, entries for Atorvastatin in the form Tablet 10 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 10 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 10 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[4] Schedule 1, Part 1, entries for Atorvastatin in the form Tablet 20 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 20 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 20 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[5] Schedule 1, Part 1, entries for Atorvastatin in the form Tablet 40 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 40 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 40 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[6] Schedule 1, Part 1, entries for Atorvastatin in the form Tablet 80 mg (as calcium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Atorvastatin | Tablet 80 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Atorvastatin | Tablet 80 mg (as calcium) | Oral | NOUMED ATORVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[7] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 2.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bisoprolol | Tablet containing bisoprolol fumarate 2.5 mg | Oral | Cipla Bisoprolol | LR | MP NP | C5324 | P5324 | 28 | 5 |  | 28 |  |  |
| Bisoprolol | Tablet containing bisoprolol fumarate 2.5 mg | Oral | Cipla Bisoprolol | LR | MP NP | C14251 | P14251 | 56 | 5 |  | 28 |  |  |

[8] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bisoprolol | Tablet containing bisoprolol fumarate 5 mg | Oral | Cipla Bisoprolol | LR | MP NP | C5324 | P5324 | 28 | 5 |  | 28 |  |  |
| Bisoprolol | Tablet containing bisoprolol fumarate 5 mg | Oral | Cipla Bisoprolol | LR | MP NP | C14251 | P14251 | 56 | 5 |  | 28 |  |  |

[9] Schedule 1, Part 1, entries for Bisoprolol in the form Tablet containing bisoprolol fumarate 10 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bisoprolol | Tablet containing bisoprolol fumarate 10 mg | Oral | Cipla Bisoprolol | LR | MP NP | C5324 | P5324 | 28 | 5 |  | 28 |  |  |
| Bisoprolol | Tablet containing bisoprolol fumarate 10 mg | Oral | Cipla Bisoprolol | LR | MP NP | C14251 | P14251 | 56 | 5 |  | 28 |  |  |

[10] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 1 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bortezomib | Powder for injection 1 mg | Injection | DBL Bortezomib | PF | MP | C11099 C13745 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[11] Schedule 1, Part 1, entries for Bortezomib in the form Powder for injection 2.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bortezomib | Powder for injection 2.5 mg | Injection | DBL Bortezomib | PF | MP | C11099 C13745 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[12] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 100 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Celecoxib | Capsule 100 mg | Oral | NOUMED CELECOXIB | VO | MP NP | C4907 C4962 |  | 60 | 3 |  | 60 |  |  |

[13] Schedule 1, Part 1, entries for Celecoxib in the form Capsule 200 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Celecoxib | Capsule 200 mg | Oral | NOUMED CELECOXIB | VO | MP NP | C4907 C4962 |  | 30 | 3 |  | 30 |  |  |

[14] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: Dasatinib ARX; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[15] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[16] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: Dasatinib Sandoz; Maximum Quantity: 60; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[17] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: Dasatinib SUN; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[18] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[19] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: Dasatinib Viatris; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[20] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 20 mg [Brand: Sprycel; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[21] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: Dasatinib ARX; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[22] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[23] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: Dasatinib Sandoz; Maximum Quantity: 60; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[24] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: Dasatinib SUN; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[25] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[26] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: Dasatinib Viatris; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[27] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 50 mg [Brand: Sprycel; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[28] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: Dasatinib ARX; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[29] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[30] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: Dasatinib Sandoz; Maximum Quantity: 60; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[31] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: Dasatinib SUN; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[32] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: DASATINIB-TEVA; Maximum Quantity: 60; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[33] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: Dasatinib Viatris; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[34] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 70 mg [Brand: Sprycel; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[35] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: Dasatinib ARX; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[36] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: Dasatinib Dr.Reddy's; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[37] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: Dasatinib Sandoz; Maximum Quantity: 30; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[38] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: Dasatinib SUN; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[39] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: DASATINIB-TEVA; Maximum Quantity: 30; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[40] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: Dasatinib Viatris; Maximum Quantity: 30; Number of
Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[41] Schedule 1, Part 1, entry for Dasatinib in the form Tablet 100 mg [Brand: Sprycel; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9367 C9468 C9469

(b) insert in numerical order in the column headed “Circumstances”: C16228 C16229 C16252

(c) omit from the column headed “Purposes”: P9367 P9468 P9469

(d) insert in numerical order in the column headed “Purposes”: P16228 P16229 P16252

[42] Schedule 1, Part 1, entries for Dimethyl fumarate in the form Capsule (modified release) 120 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dimethyl fumarate | Capsule (modified release) 120 mg | Oral | Dimethyl Fumarate MSN | LR | MP | C10139 C10140 |  | 28 | 0 |  | 14 |  |  |

[43] Schedule 1, Part 1, entries for Dimethyl fumarate in the form Capsule (modified release) 240 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Dimethyl fumarate | Capsule (modified release) 240 mg | Oral | Dimethyl Fumarate MSN | LR | MP | C10139 |  | 56 | 5 |  | 56 |  |  |

[44] Schedule 1, Part 1, entries for Duloxetine in the form Capsule 30 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Duloxetine | Capsule 30 mg (as hydrochloride) | Oral | Cymbalta | LY | MP NP | C5650 |  | 28 | 0 |  | 28 |  |  |

[45] Schedule 1, Part 1, entries for Duloxetine in the form Capsule 60 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Duloxetine | Capsule 60 mg (as hydrochloride) | Oral | Cymbalta | LY | MP NP | C5650 |  | 28 | 5 |  | 28 |  |  |

[46] Schedule 1, Part 1, entry for Enzalutamide [Maximum Quantity: 112; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C12937 substitute: C16233

(b) omit from the column headed “Purposes”: P12937 substitute: P16233

[47] Schedule 1, Part 1, after entry for Erlotinib in the form Tablet 150 mg (as hydrochloride) [Brand: Erlotinib APOTEX]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Erlotinib | Tablet 150 mg (as hydrochloride) | Oral | ERLOTINIB ARX | XT | MP | C4473 C4600 C7446 |  | 30 | 3 |  | 30 |  |  |

[48] Schedule 1, Part 1, entries for Escitalopram in the form Tablet 10 mg (as oxalate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Escitalopram | Tablet 10 mg (as oxalate) | Oral | NOUMED ESCITALOPRAM | VO | MP NP | C4690 C4703 C4755 C4756 C4757 | P4690 P4703 P4755 P4756 P4757 | 28 | 5 |  | 28 |  |  |
| Escitalopram | Tablet 10 mg (as oxalate) | Oral | NOUMED ESCITALOPRAM | VO | MP NP | C15550 C15551 C15666 C15669 C15696 | P15550 P15551 P15666 P15669 P15696 | 56 | 2 |  | 28 |  |  |

[49] Schedule 1, Part 1, entries for Escitalopram in the form Tablet 20 mg (as oxalate)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Escitalopram | Tablet 20 mg (as oxalate) | Oral | NOUMED ESCITALOPRAM | VO | MP NP | C4690 C4703 C4755 C4756 C4757 | P4690 P4703 P4755 P4756 P4757 | 28 | 5 |  | 28 |  |  |
| Escitalopram | Tablet 20 mg (as oxalate) | Oral | NOUMED ESCITALOPRAM | VO | MP NP | C15550 C15551 C15666 C15669 C15696 | P15550 P15551 P15666 P15669 P15696 | 56 | 2 |  | 28 |  |  |

[50] Schedule 1, Part 1, entries for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)

(a) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP NP | C8774 C8775 | P8774 P8775 | 30 | 1 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP NP | C8776 C8780 C8827 | P8776 P8780 P8827 | 30 | 5 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP | C11310 | P11310 | 60 | 5 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP NP | C15530 C15658 C15682 | P15530 P15658 P15682 | 60 | 5 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP | C15856 | P15856 | 120 | 5 |  | 30 |  |  |

(b) omit from the column headed “Form” (all instances): Tablet (enteric coated) 20 mg (as magnesium trihydrate)

 *substitute (all instances):* Tablet (enteric coated) 20 mg (as magnesium)

[51] Schedule 1, Part 1, entries for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)

(a) omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP NP | C8902 | P8902 | 30 | 1 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP NP | C8777 C8778 | P8777 P8778 | 30 | 5 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP | C11370 | P11370 | 60 | 5 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP NP | C15655 C15704 | P15655 P15704 | 60 | 5 |  | 30 |  |  |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | Oral | Esomeprazole Mylan | AL | MP | C15936 | P15936 | 120 | 5 |  | 30 |  |  |

(b) omit from the column headed “Form” (all instances): Tablet (enteric coated) 40 mg (as magnesium trihydrate)

 substitute (all instances): Tablet (enteric coated) 40 mg (as magnesium)

[52] Schedule 1, Part 1, entry for Famciclovir in the form Tablet 500 mg *[Brand: Ezovir]*

omit from the column headed “Responsible Person”: AF substitute: XT

[53] Schedule 1, Part 1, entries for Fingolimod in the form Capsule 500 micrograms (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fingolimod | Capsule 500 micrograms (as hydrochloride) | Oral | FINGOLIS | LR | MP | C10162 C10172 |  | 28 | 5 |  | 28 |  |  |

[54] Schedule 1, Part 1, entries for Fluoxetine in the form Capsule 20 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Fluoxetine | Capsule 20 mg (as hydrochloride) | Oral | NOUMED FLUOXETINE | VO | MP NP | C4755 C6277 | P4755 P6277 | 28 | 5 |  | 28 |  |  |
| Fluoxetine | Capsule 20 mg (as hydrochloride) | Oral | NOUMED FLUOXETINE | VO | MP NP | C15582 C15666 | P15582 P15666 | 56 | 2 |  | 28 |  |  |
| Fluoxetine | Capsule 20 mg (as hydrochloride) | Oral | Prozac 20 | LY | MP NP | C4755 C6277 | P4755 P6277 | 28 | 5 |  | 28 |  |  |
| Fluoxetine | Capsule 20 mg (as hydrochloride) | Oral | Prozac 20 | LY | MP NP | C15582 C15666 | P15582 P15666 | 56 | 2 |  | 28 |  |  |

[55] Schedule 1, Part 1, entries for Hypromellose in the form Eye drops 3 mg per mL, 10 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hypromellose | Eye drops 3 mg per mL, 10 mL | Application to the eye | Genteal | AQ | MP NP AO | C15560 | P15560 | 1 | 5 |  | 1 |  |  |
| Hypromellose | Eye drops 3 mg per mL, 10 mL | Application to the eye | Genteal | AQ | MP NP AO | C15556 | P15556 | 2 | 5 |  | 1 |  |  |
| Hypromellose | Eye drops 3 mg per mL, 10 mL | Application to the eye | In a Wink Moisturising | IQ | MP NP AO | C15560 | P15560 | 1 | 5 |  | 1 |  |  |
| Hypromellose | Eye drops 3 mg per mL, 10 mL | Application to the eye | In a Wink Moisturising | IQ | MP NP AO | C15556 | P15556 | 2 | 5 |  | 1 |  |  |

[56] Schedule 1, Part 1, omit entries for Hypromellose with carbomer 980

[57] Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: ARX-IMATINIB; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[58] Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: Imatinib-APOTEX; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[59] Schedule 1, Part 1, entry for Imatinib in the form Capsule 100 mg (as mesilate) [Brand: IMATINIB-DRLA; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[60] Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: ARX-IMATINIB; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[61] Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: Imatinib GH; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[62] Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: Imatinib-APOTEX; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[63] Schedule 1, Part 1, entry for Imatinib in the form Capsule 400 mg (as mesilate) [Brand: IMATINIB-DRLA; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[64] Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Brand: Gilmat; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[65] Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Brand: Glivec; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[66] Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Brand: Imanib; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[67] Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Brand: IMATINIB RBX; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[68] Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Brand: Imatinib Sandoz; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[69] Schedule 1, Part 1, entry for Imatinib in the form Tablet 100 mg (as mesilate) [Brand: Imatinib-Teva; Maximum Quantity: 60; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[70] Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Brand: Gilmat; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[71] Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Brand: Glivec; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[72] Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Brand: Imanib; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[73] Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Brand: IMATINIB RBX; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[74] Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Brand: Imatinib Sandoz; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[75] Schedule 1, Part 1, entry for Imatinib in the form Tablet 400 mg (as mesilate) [Brand: Imatinib-Teva; Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[76] Schedule 1, Part 1, entry for Imatinib in the form Tablet 600 mg (as mesilate) [Maximum Quantity: 30; Number of Repeats: 2]

(a) omit from the column headed “Circumstances”: C9203 C9207

(b) insert in numerical order in the column headed “Circumstances”: C16238 C16249

(c) omit from the column headed “Purposes”: P9203 P9207

(d) insert in numerical order in the column headed “Purposes”: P16238 P16249

[77] Schedule 1, Part 1, entry for Ketoprofen *[Maximum Quantity: 28; Number of Repeats: 0]*

insert in the column headed “Purposes”: P6214

[78] Schedule 1, Part 1, entry for Ketoprofen *[Maximum Quantity: 28; Number of Repeats: 3]*

insert in the column headed “Purposes”: P6214

[79] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lamotrigine | Tablet 25 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C11081 | P11081 | 56 | 5 |  | 56 |  |  |
| Lamotrigine | Tablet 25 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C14855 | P14855 | 112 | 5 |  | 56 |  |  |

[80] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lamotrigine | Tablet 50 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C11081 | P11081 | 56 | 5 |  | 56 |  |  |
| Lamotrigine | Tablet 50 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C14855 | P14855 | 112 | 5 |  | 56 |  |  |

[81] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 100 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lamotrigine | Tablet 100 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C11081 | P11081 | 56 | 5 |  | 56 |  |  |
| Lamotrigine | Tablet 100 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C14855 | P14855 | 112 | 5 |  | 56 |  |  |

[82] Schedule 1, Part 1, entries for Lamotrigine in the form Tablet 200 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lamotrigine | Tablet 200 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C11081 | P11081 | 56 | 5 |  | 56 |  |  |
| Lamotrigine | Tablet 200 mg | Oral | NOUMED LAMOTRIGINE | VO | MP NP | C14855 | P14855 | 112 | 5 |  | 56 |  |  |

[83] Schedule 1, Part 1, entries for Lansoprazole in the form Capsule 30 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lansoprazole | Capsule 30 mg | Oral | NOUMED LANSOPRAZOLE | VO | MP NP | C8774 C8775 | P8774 P8775 | 28 | 1 |  | 28 |  |  |
| Lansoprazole | Capsule 30 mg | Oral | NOUMED LANSOPRAZOLE | VO | MP NP | C8776 C8780 | P8776 P8780 | 28 | 5 |  | 28 |  |  |
| Lansoprazole | Capsule 30 mg | Oral | NOUMED LANSOPRAZOLE | VO | MP NP | C11310 C15530 C15658 | P11310 P15530 P15658 | 56 | 5 |  | 28 |  |  |
| Lansoprazole | Capsule 30 mg | Oral | NOUMED LANSOPRAZOLE | VO | MP | C15856 | P15856 | 112 | 5 |  | 28 |  |  |

[84] Schedule 1, Part 1, entry for Liothyronine *[Maximum Quantity: 200; Number of Repeats: 2]*

(a) omit from the column headed “Circumstances”: C15038

(b) omit from the column headed “Purposes”: P15038

[85] Schedule 1, Part 1, entries for Metformin in the form Tablet containing metformin hydrochloride 500 mg *[Brand: APX-Metformin]*

omit from the column headed “Brand”: APX-Metformin substitute: APX-METFORMIN

[86] Schedule 1, Part 1, entries for Metformin in the form Tablet containing metformin hydrochloride 850 mg *[Brand: APX-Metformin]*

omit from the column headed “Brand”: APX-Metformin substitute: APX-METFORMIN

[87] Schedule 1, Part 1, entries for Metformin in the form Tablet containing metformin hydrochloride 1 g *[Brand: APX-Metformin]*

omit from the column headed “Brand”: APX-Metformin substitute: APX-METFORMIN

[88] Schedule 1, Part 1, entries for Metoprolol in the form Tablet containing metoprolol tartrate 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metoprolol | Tablet containing metoprolol tartrate 50 mg | Oral | NOUMED METOPROLOL | VO | MP NP |  |  | 100 | 5 |  | 100 |  |  |
| Metoprolol | Tablet containing metoprolol tartrate 50 mg | Oral | NOUMED METOPROLOL | VO | MP NP |  | P14238 | 200 | 5 |  | 100 |  |  |

[89] Schedule 1, Part 1, entries for Metoprolol in the form Tablet containing metoprolol tartrate 100 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Metoprolol | Tablet containing metoprolol tartrate 100 mg | Oral | NOUMED METOPROLOL | VO | MP NP |  |  | 60 | 5 |  | 60 |  |  |
| Metoprolol | Tablet containing metoprolol tartrate 100 mg | Oral | NOUMED METOPROLOL | VO | MP NP |  | P14238 | 120 | 5 |  | 60 |  |  |

[90] Schedule 1, Part 1, entries for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Mycophenolic acid | Capsule containing mycophenolate mofetil 250 mg | Oral | Ceptolate | AF | MP |  |  | 300 | 5 |  | 50 |  |  |
| Mycophenolic acid | Capsule containing mycophenolate mofetil 250 mg | Oral | Ceptolate | AF | MP |  | P14238 | 600 | 5 |  | 50 |  |  |

[91] Schedule 1, Part 1, entries for Nivolumab

insert in the column headed “Variations” (all instances): V15527

[92] Schedule 1, Part 1, entries for Nortriptyline in the form Tablet 10 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nortriptyline | Tablet 10 mg (as hydrochloride) | Oral | NortriTABS 10 mg | GH | MP NP | C6235 C6300 |  | 50 | 2 |  | 50 |  |  |

[93] Schedule 1, Part 1, entries for Nortriptyline in the form Tablet 25 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Nortriptyline | Tablet 25 mg (as hydrochloride) | Oral | NortriTABS 25 mg | GH | MP NP | C6235 C6300 |  | 50 | 2 |  | 50 |  |  |

[94] Schedule 1, Part 1, entry for Olaparib in the form Tablet 100 mg [Maximum Quantity: 112; Number of Repeats: 5]

(a) omit from the column headed “Circumstances”: C15370

(b) insert in numerical order in the column headed “Circumstances”: C16234 C16240 C16241

(c) omit from the column headed “Purposes”: P15370

(d) insert in numerical order in the column headed “Purposes”: P16234 P16240 P16241

[95] Schedule 1, Part 1, entry for Olaparib in the form Tablet 150 mg [Maximum Quantity: 112; Number of Repeats: 5]

(a) omit from the column headed “Circumstances”: C15370

(b) insert in numerical order in the column headed “Circumstances”: C16234 C16240 C16241

(c) omit from the column headed “Purposes”: P15370

(d) insert in numerical order in the column headed “Purposes”: P16234 P16240 P16241

[96] Schedule 1, Part 1, entries for Paracetamol in the form Tablet 500 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Paracetamol | Tablet 500 mg | Oral | Parapane | AF | PDP | C5846 | P5846 | 100 | 0 |  | 100 |  |  |
| Paracetamol | Tablet 500 mg | Oral | Parapane | AF | MP NP | C5835 | P5835 | 100 | 1 |  | 100 |  |  |
| Paracetamol | Tablet 500 mg | Oral | Parapane | AF | PDP | C5885 | P5885 | 300 | 0 |  | 100 |  |  |
| Paracetamol | Tablet 500 mg | Oral | Parapane | AF | MP NP | C5865 | P5865 | 300 | 4 |  | 100 |  |  |

[97] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 125 mg *[Maximum Quantity: 200; Number of Repeats: 1]*

omit from the column headed “Purposes”: P14238  substitute: P16078

[98] Schedule 1, Part 1, entry for Penicillamine in the form Tablet 250 mg *[Maximum Quantity: 200; Number of Repeats: 1]*

omit from the column headed “Purposes”: P14238  substitute: P16078

[99] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 25 mg | Oral | NOUMED PREGABALIN | VO | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

[100] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 75 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 75 mg | Oral | NOUMED PREGABALIN | VO | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

[101] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 150 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 150 mg | Oral | NOUMED PREGABALIN | VO | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

[102] Schedule 1, Part 1, entries for Pregabalin in the form Capsule 300 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Pregabalin | Capsule 300 mg | Oral | NOUMED PREGABALIN | VO | MP NP | C4172 |  | 56 | 5 |  | 56 |  |  |

[103] Schedule 1, Part 1, after entry for Risedronic acid in the form Tablet containing risedronate sodium 150 mg *[Brand: APO-Risedronate; Maximum Quantity: 2; Number of Repeats: 5]*

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Risperidone | I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 75 mg and 1 pre-filled syringe diluent 383 microlitres | Injection | Risvan | SE | MP NP | C16231 |  | 1 | 5 |  | 1 |  |  |
| Risperidone | I.M. injection (modified release), set containing 1 pre-filled syringe powder for injection 100 mg and 1 pre-filled syringe diluent 490 microlitres | Injection | Risvan | SE | MP NP | C16231 |  | 1 | 5 |  | 1 |  |  |

[104] Schedule 1, Part 1, entries for Safinamide

omit from the column headed “Responsible Person” (all instances): CS substitute (all instances): IX

[105] Schedule 1, Part 1, entries for Sertraline in the form Tablet 50 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sertraline | Tablet 50 mg (as hydrochloride) | Oral | NOUMED SERTRALINE | VO | MP NP | C4755 C6277 C6289 | P4755 P6277 P6289 | 30 | 5 |  | 30 |  |  |
| Sertraline | Tablet 50 mg (as hydrochloride) | Oral | NOUMED SERTRALINE | VO | MP NP | C15582 C15583 C15666 | P15582 P15583 P15666 | 60 | 2 |  | 30 |  |  |

[106] Schedule 1, Part 1, entries for Sertraline in the form Tablet 100 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sertraline | Tablet 100 mg (as hydrochloride) | Oral | NOUMED SERTRALINE | VO | MP NP | C4755 C6277 C6289 | P4755 P6277 P6289 | 30 | 5 |  | 30 |  |  |
| Sertraline | Tablet 100 mg (as hydrochloride) | Oral | NOUMED SERTRALINE | VO | MP NP | C15582 C15583 C15666 | P15582 P15583 P15666 | 60 | 2 |  | 30 |  |  |

[107] Schedule 1, Part 1, entries for Simvastatin in the form Tablet 10 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Simvastatin | Tablet 10 mg | Oral | NOUMED SIMVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Simvastatin | Tablet 10 mg | Oral | NOUMED SIMVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[108] Schedule 1, Part 1, entries for Simvastatin in the form Tablet 20 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Simvastatin | Tablet 20 mg | Oral | NOUMED SIMVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Simvastatin | Tablet 20 mg | Oral | NOUMED SIMVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[109] Schedule 1, Part 1, entries for Simvastatin in the form Tablet 40 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Simvastatin | Tablet 40 mg | Oral | NOUMED SIMVASTATIN | VO | MP NP |  |  | 30 | 5 |  | 30 |  |  |
| Simvastatin | Tablet 40 mg | Oral | NOUMED SIMVASTATIN | VO | MP NP |  | P14238 | 60 | 5 |  | 30 |  |  |

[110] Schedule 1, Part 1, after entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride [Brand: Sitagliptin/Metformin Sandoz; Maximum Quantity: 112; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | SITAGLO-MET | CR | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride | Oral | SITAGLO-MET | CR | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |

[111] Schedule 1, Part 1, after entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride [Brand: Sitagliptin/Metformin Sandoz; Maximum Quantity: 112; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | SITAGLO-MET | CR | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride | Oral | SITAGLO-MET | CR | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |

[112] Schedule 1, Part 1, after entry for Sitagliptin with metformin in the form Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride [Brand: Sitagliptin/Metformin Sandoz; Maximum Quantity: 112; Number of Repeats: 5]

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | SITAGLO-MET | CR | MP NP | C15276 | P15276 | 56 | 5 |  | 56 |  |  |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride | Oral | SITAGLO-MET | CR | MP NP | C15288 | P15288 | 112 | 5 |  | 56 |  |  |

[113] Schedule 1, Part 1, entries for Somatropin in the form Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative)

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Somatropin | Powder for injection 5 mg (15 i.u.) with diluent in pre-filled pen (with preservative) | Injection | Genotropin GoQuick | PF | MP | C12703 C12704 C12705 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12738 C12758 C12760 C12765 C12768 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12791 C12793 C12798 C12803 C12812 C12829 C12831 C12832 C12834 C12858 C12860 C12866 C12867 C12869 C12884 C12887 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[114] Schedule 1, Part 1, entries for Somatropin in the form Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative)

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Somatropin | Powder for injection 12 mg (36 i.u.) with diluent in pre-filled pen (with preservative) | Injection | Genotropin GoQuick | PF | MP | C12703 C12704 C12705 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12738 C12758 C12760 C12765 C12768 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12791 C12793 C12798 C12803 C12812 C12829 C12831 C12832 C12834 C12858 C12860 C12866 C12867 C12869 C12884 C12887 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[115] Schedule 1, Part 1, entries for Somatropin in the form Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Somatropin | Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen | Injection | Norditropin FlexPro | NO | MP | C12703 C12704 C12711 C12712 C12722 C12723 C12725 C12726 C12731 C12738 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12798 C12803 C12812 C12829 C12831 C12832 C12834 C12858 C12860 C12866 C12867 C12884 C12929 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[116] Schedule 1, Part 1, entries for Somatropin in the form Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Somatropin | Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative) | Injection | Saizen | SG | MP | C12703 C12704 C12711 C12712 C12721 C12722 C12723 C12725 C12726 C12731 C12738 C12749 C12752 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12803 C12806 C12831 C12832 C12834 C12858 C12860 C12861 C12866 C12884 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[117] Schedule 1, Part 1, entries for Somatropin in the form Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Somatropin | Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative) | Injection | Saizen | SG | MP | C12703 C12704 C12711 C12712 C12721 C12722 C12723 C12725 C12726 C12731 C12738 C12749 C12752 C12758 C12760 C12765 C12769 C12770 C12771 C12774 C12775 C12779 C12780 C12784 C12785 C12803 C12806 C12831 C12832 C12834 C12858 C12860 C12861 C12866 C12884 C13288 C13309 C13346 C13350 C13352 C13353 C13355 C13356 C13359 C13360 C13363 C13364 C14366 C16226 C16242 C16243 |  | See Note 3 | See Note 3 |  | 1 |  | D(100) |

[118] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 12.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sunitinib | Capsule 12.5 mg | Oral | Sunitinib MSN | LR | MP | C11878 C13152 C13153 |  | 28 | 1 |  | 28 |  |  |
| Sunitinib | Capsule 12.5 mg | Oral | Sunitinib MSN | LR | MP | C4862 |  | 28 | 2 |  | 28 |  |  |
| Sunitinib | Capsule 12.5 mg | Oral | Sunitinib MSN | LR | MP | C11875 |  | 28 | 3 |  | 28 |  |  |
| Sunitinib | Capsule 12.5 mg | Oral | Sunitinib MSN | LR | MP | C7471 |  | 28 | 5 |  | 28 |  |  |

[119] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 25 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sunitinib | Capsule 25 mg | Oral | Sunitinib MSN | LR | MP | C11878 C13152 C13153 |  | 28 | 1 |  | 28 |  |  |
| Sunitinib | Capsule 25 mg | Oral | Sunitinib MSN | LR | MP | C4862 |  | 28 | 2 |  | 28 |  |  |
| Sunitinib | Capsule 25 mg | Oral | Sunitinib MSN | LR | MP | C11875 |  | 28 | 3 |  | 28 |  |  |
| Sunitinib | Capsule 25 mg | Oral | Sunitinib MSN | LR | MP | C7471 |  | 28 | 5 |  | 28 |  |  |

[120] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 37.5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sunitinib | Capsule 37.5 mg | Oral | Sunitinib MSN | LR | MP | C11878 C13152 C13153 |  | 28 | 1 |  | 28 |  |  |
| Sunitinib | Capsule 37.5 mg | Oral | Sunitinib MSN | LR | MP | C4862 |  | 28 | 2 |  | 28 |  |  |
| Sunitinib | Capsule 37.5 mg | Oral | Sunitinib MSN | LR | MP | C11875 |  | 28 | 3 |  | 28 |  |  |
| Sunitinib | Capsule 37.5 mg | Oral | Sunitinib MSN | LR | MP | C7471 |  | 28 | 5 |  | 28 |  |  |

[121] Schedule 1, Part 1, entries for Sunitinib in the form Capsule 50 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sunitinib | Capsule 50 mg | Oral | Sunitinib MSN | LR | MP | C11878 C13152 C13153 |  | 28 | 1 |  | 28 |  |  |
| Sunitinib | Capsule 50 mg | Oral | Sunitinib MSN | LR | MP | C4862 |  | 28 | 2 |  | 28 |  |  |
| Sunitinib | Capsule 50 mg | Oral | Sunitinib MSN | LR | MP | C11875 |  | 28 | 3 |  | 28 |  |  |
| Sunitinib | Capsule 50 mg | Oral | Sunitinib MSN | LR | MP | C7471 |  | 28 | 5 |  | 28 |  |  |

[122] Schedule 1, Part 1, after entry for Tafamidis

insert:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Talazoparib | Capsule 100 micrograms (as tosilate) | Oral | Talzenna | PF | MP | C16224 |  | 30 | 5 |  | 30 |  |  |
| Talazoparib | Capsule 250 micrograms (as tosilate) | Oral | Talzenna | PF | MP | C16224 |  | 30 | 5 |  | 30 |  |  |
| Talazoparib | Capsule 350 micrograms (as tosilate) | Oral | Talzenna | PF | MP | C16224 |  | 30 | 5 |  | 30 |  |  |
| Talazoparib | Capsule 500 micrograms (as tosilate) | Oral | Talzenna | PF | MP | C16224 |  | 30 | 5 |  | 30 |  |  |

[123] Schedule 1, Part 1, entries for Telmisartan in the form Tablet 80 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Telmisartan | Tablet 80 mg | Oral | NOUMED TELMISARTAN | VO | MP NP |  |  | 28 | 5 |  | 28 |  |  |
| Telmisartan | Tablet 80 mg | Oral | NOUMED TELMISARTAN | VO | MP NP |  | P14238 | 56 | 5 |  | 28 |  |  |

[124] Schedule 1, Part 1, entry for Tofacitinib in the form Oral solution 1 mg per mL, 240 mL *[Maximum Quantity: 1; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C14647

(b) omit from the column headed “Purposes”: P14647

[125] Schedule 1, Part 1, entry for Tofacitinib in the form Tablet 5 mg *[Maximum Quantity: 56; Number of Repeats: 5]*

(a) omit from the column headed “Circumstances”: C14647

(b) omit from the column headed “Purposes”: P14647

[126] Schedule 1, Part 1, entry for Ustekinumab in the form Injection 90 mg in 1 mL single use pre-filled syringe *[Maximum Quantity: 1; Number of Repeats: 1]*

(a) omit from the column headed “Circumstances”: C14802

(b) omit from the column headed “Purposes”: P14802

[127] Schedule 1, Part 2, omit entry for Acalabrutinib

[128] Schedule 1, Part 2, after entry for Glucose indicator-urine

insert:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hypromellose with carbomer 980 | Ocular lubricating gel 3 mg-2 mg per g, 10 g | Application to the eye | Genteal gel | AQ | 1 |  |  |
| Hypromellose with carbomer 980 | Ocular lubricating gel 3 mg-2 mg per g, 10 g | Application to the eye | HPMC PAA | IQ | 1 |  |  |

[129] Schedule 4, Part 1, omit entry for Circumstances Code “C9203”

[130] Schedule 4, Part 1, omit entry for Circumstances Code “C9207”

[131] Schedule 4, Part 1, omit entry for Circumstances Code “C9367”

[132] Schedule 4, Part 1, omit entry for Circumstances Code “C9468”

[133] Schedule 4, Part 1, omit entry for Circumstances Code “C9469”

[134] Schedule 4, Part 1, omit entry for Circumstances Code “C12588”

[135] Schedule 4, Part 1, omit entry for Circumstances Code “C12937”

[136] Schedule 4, Part 1, omit entry for Circumstances Code “C14390”

[137] Schedule 4, Part 1, omit entry for Circumstances Code “C14431”

[138] Schedule 4, Part 1, omit entry for Circumstances Code “C14647”

[139] Schedule 4, Part 1, omit entry for Circumstances Code “C14802”

[140] Schedule 4, Part 1, omit entry for Circumstances Code “C15038”

[141] Schedule 4, Part 1, omit entry for Circumstances Code “C15370”

[142] Schedule 4, Part 1, entry for Circumstances Code “C15560”

omit from the column headed “Listed Drug”: Hypromellose with carbomer 980

[143] Schedule 4, Part 1, omit entry for Circumstances Code “C15640”

[144] Schedule 4, Part 1, entry for Circumstance Code “C16094”

omit entry for Circumstances Code “C16094” and substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C16094 | P16094 | CN16094 | Voriconazole | Serious fungal infectionsTreatment and maintenance therapyThe condition must be caused by Scedosporium species; ORThe condition must be caused by Fusarium species.Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner. | Compliance with Authority Required procedures |

[145] Schedule 4, Part 1, entry for Circumstances Code “C16189”

omit entry for Circumstances Code “C16189” and substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C16189 | P16189 | CN16189 | Methylphenidate | Attention deficit hyperactivity disorderPatient must have demonstrated a response to immediate-release methylphenidate hydrochloride with no emergence of serious adverse events; ANDPatient must require continuous coverage over 12 hours; ANDThe treatment must not exceed a maximum daily dose of 72 mg of PBS-subsidised treatment with this drug.Patient must be or have been diagnosed between the ages of 6 and 18 years inclusive. | Compliance with Authority Required procedures |

[146] Schedule 4, Part 1, after entry for Circumstances Code “C16223”

insert:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| C16224 | P16224 | CN16224 | Talazoparib | Castration resistant metastatic carcinoma of the prostateThe condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation; ANDPatient must not have received prior PBS-subsidised novel hormonal drug in any non-metastatic setting of prostate cancer prior to commencing treatment with this drug for this condition; ANDPatient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance score no higher than 1 prior to treatment initiation; ANDPatient must be undergoing concurrent treatment with enzalutamide, unless an intolerance to enzalutamide requires either a: (i) temporary cessation, (ii) permanent discontinuation; ANDThe treatment must not be a PBS-subsidised benefit beyond disease progression. | Compliance with Authority Required procedures |
| C16226 | P16226 | CN16226 | Somatropin | Severe growth hormone deficiencyInitial treatment of late onset growth hormone deficiencyMust be treated by an endocrinologist; ANDPatient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; orPatient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years; ANDPatient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre. orPatient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre. orPatient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre. orPatient must have: (a) a chronological age of 18 years or older, (b) established hypothalamic-pituitary disease, (c) at least three documented pituitary hormone deficiencies, (d) an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient.The authority application must be in writing and must include:Details of the proposed prescription; ANDA completed Severe Growth Hormone Deficiency supporting information form; ANDIf applicable, results of the growth hormone simulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender. | Compliance with Written Authority Required procedures |
| C16228 | P16228 | CN16228 | Dasatinib | Acute lymphoblastic leukaemiaMaintenance of first complete remissionPatient must have previously received PBS-subsidised treatment with this drug for this condition; orPatient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with imatinib as a first-line therapy for this condition; ANDThe condition must be expressing the Philadelphia chromosome; orThe condition must have the transcript BCR-ABL; ANDPatient must not have developed disease progression while receiving treatment with this drug for this condition; ANDPatient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose. orPatient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.Conditions for PBS-subsidy beyond 24 months of treatment On the first occasion an authority application extends PBS-subsidy beyond 24 months, confirm that 1) The condition is expressing the Philadelphia chromosome,2) Measurable residual disease (MRD) is present,3) MRD has been confirmed in at least one of (i) marrow, (ii) peripheral blood,4) MRD has been confirmed within the preceding 6 months of this authority application,5) MRD has been ascertained by at least one of (i) a molecular method, (ii) flow cytometry,6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable. | Compliance with Authority Required procedures |
| C16229 | P16229 | CN16229 | Dasatinib | Acute lymphoblastic leukaemiaInduction and Consolidation therapyPatient must be newly diagnosed; ANDThe condition must be expressing the Philadelphia chromosome; orThe condition must have the transcript BCR-ABL; ANDThe treatment must be in combination with chemotherapy or corticosteroids; ANDPatient must not have previously experienced a failure to respond to the PBS-subsidised first line treatment with this drug for this condition. orPatient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with imatinib as a first-line therapy for this condition.The authority application must be made in writing and must include (a) details of the proposed prescription; and(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and(c) a pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia to confirm eligibility for treatment, with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow. (The date of the relevant pathology report needs to be provided). | Compliance with Written Authority Required procedures |
| C16231 | P16231 | CN16231 | Risperidone | SchizophreniaFor a patient switching from oral risperidone, the prescriber must determine the patient dosage of this drug based on the current dose of oral risperidone according to the dose transition table in the Therapeutic Goods Administration (TGA) approved Product Information. | Compliance with Authority Required procedures - Streamlined Authority Code 16231 |
| C16233 | P16233 | CN16233 | Enzalutamide | Castration resistant metastatic carcinoma of the prostateThe treatment must not be used in combination with chemotherapy; ANDPatient must have a WHO performance status of 2 or less; ANDPatient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug; ANDPatient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication). orPatient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation. orPatient must have been receiving PBS-subsidised treatment with abiraterone or abiraterone plus methylprednisolone for castration resistant metastatic prostate cancer prior to being associated with a class 4 or 5 BRCA1 or BRCA2 gene mutation. | Compliance with Authority Required procedures |
| C16234 | P16234 | CN16234 | Olaparib | Metastatic breast cancerInitial treatmentThe condition must be human epidermal growth factor receptor 2 (HER2) negative; ANDThe condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant; ANDPatient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; ANDPatient must have received chemotherapy in the neoadjuvant, adjuvant or metastatic setting; ANDPatient must not have received PBS-subsidised treatment with this drug in any earlier line of treatment for breast cancer; ANDThe condition must be triple negative breast cancer; orThe condition must be hormone-receptor positive breast cancer and the patient has either: (i) progressive disease after receiving endocrine therapy, (ii) been considered inappropriate for endocrine therapy; ANDThe treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.Retain all pathology imaging and investigative test results in the patient's medical records. Do not submit copies of these as part of the authority application.Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C16238 | P16238 | CN16238 | Imatinib | Acute lymphoblastic leukaemiaInduction and Consolidation therapyPatient must be newly diagnosed; ANDThe condition must be expressing the Philadelphia chromosome; orThe condition must have the transcript BCR-ABL; ANDThe treatment must be in combination with chemotherapy or corticosteroids; ANDPatient must not have previously experienced a failure to respond to PBS-subsidised first-line treatment with this drug for this condition. orPatient must have experienced intolerance, not a failure to respond, to initial PBS-subsidised treatment with dasatinib as a first-line therapy for this condition.A pathology cytogenetic report conducted on peripheral blood or bone marrow supporting the diagnosis of acute lymphoblastic leukaemia with either cytogenetic evidence of the Philadelphia chromosome, or a qualitative PCR report documenting the presence of the BCR-ABL transcript in either peripheral blood or bone marrow must be documented in the patient's medical records. | Compliance with Authority Required procedures |
| C16240 | P16240 | CN16240 | Olaparib | Early breast cancerInitial treatmentThe condition must be human epidermal growth factor receptor 2 (HER2) negative; ANDPatient must have received neoadjuvant or adjuvant chemotherapy; ANDThe treatment must be adjuvant to surgical resection; ANDThe condition must be associated with a class 4 or 5 BRCA1 or BRCA2 gene variant; ANDPatient must have received neoadjuvant chemotherapy, and residual invasive cancer is confirmed in the breast and/or resected lymph nodes (pathological complete response was not achieved); orPatient must have received adjuvant chemotherapy for triple negative breast cancer, and has either: (a) node positive disease is present, (b) a primary tumour greater than 20 mm; orPatient must have received adjuvant chemotherapy for hormone receptor positive breast cancer, and has at least 4 positive lymph nodes; ANDThe treatment must not be a PBS-subsidised benefit beyond the following, whichever comes first: (i) a total of 52 weeks of treatment (including any non-PBS-subsidised supply), (ii) disease recurrence. Mark any remaining repeat prescriptions with the word 'cancelled' where (i)/ (ii) has occurred; ANDThe treatment must be commenced within 12 weeks of completing other therapy noting that other therapy can be any of the following therapy: (i) surgery, (ii) radiotherapy, (iii) chemotherapy; ANDThe treatment must not be in combination with any of the following: (i) abemaciclib, (ii) pembrolizumab.Retain all pathology imaging and investigative test results in the patient's medical records.Treatment with this drug for this condition is restricted to one line of therapy at any disease staging for breast cancer (i.e. if therapy has been prescribed for early disease, subsidy under metastatic disease is no longer available). | Compliance with Authority Required procedures |
| C16241 | P16241 | CN16241 | Olaparib | Metastatic breast cancerContinuing treatmentPatient must have received previous PBS-subsidised treatment with this drug in the metastatic setting; ANDThe treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; ANDPatient must not have developed disease progression while receiving treatment with this drug for this condition. | Compliance with Authority Required procedures |
| C16242 | P16242 | CN16242 | Somatropin | Severe growth hormone deficiencyInitial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a childMust be treated by an endocrinologist; ANDPatient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; ANDPatient must have previously received PBS-subsidised treatment with this drug for this condition as a child;Patient must have a mature skeleton.Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.The authority application must be in writing and must include:Details of the proposed prescription; ANDA completed Severe Growth Hormone Deficiency supporting information form. | Compliance with Written Authority Required procedures |
| C16243 | P16243 | CN16243 | Somatropin | Severe growth hormone deficiencyInitial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a childMust be treated by an endocrinologist; ANDPatient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause; ANDPatient must have previously received non-PBS subsidised treatment with this drug for this condition as a child; ANDPatient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; orPatient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; orPatient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre;Patient must have a mature skeleton.Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.The authority application must be in writing and must include:Details of the proposed prescription; ANDA completed Severe Growth Hormone Deficiency supporting information form; ANDResults of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender. | Compliance with Written Authority Required procedures |
| C16249 | P16249 | CN16249 | Imatinib | Acute lymphoblastic leukaemiaMaintenance of first complete remissionPatient must have previously received PBS-subsidised treatment with this drug for this condition; orPatient must have experienced intolerance, not a failure to respond, to continuing PBS-subsidised treatment with dasatinib as a first-line therapy for this condition; ANDThe condition must be expressing the Philadelphia chromosome; orThe condition must have the transcript BCR-ABL; ANDPatient must not have developed disease progression while receiving treatment with this drug for this condition; ANDPatient must be undergoing treatment with this drug that is occurring within the first 24 months from the first administered dose. orPatient must be undergoing treatment with this drug that is occurring beyond the first 24 months from the first administered dose - the patient meets the conditions as outlined below.Conditions for PBS-subsidy beyond 24 months of treatment On the first occasion an authority application extends PBS-subsidy beyond 24 months, by annotating the prescription with the Streamlined Authority Required code, the prescriber is declaring that 1) The condition is expressing the Philadelphia chromosome,2) Measurable residual disease (MRD) is present,3) MRD has been confirmed in at least one of (i) marrow, (ii) peripheral blood,4) MRD has been confirmed within the preceding months of this authority application,5) MRD has been ascertained by at least one of (i) a molecular method, (ii) flow cytometry,6) Allogenic stem cell transplantation is considered by the prescriber to be unsuitable for the patient.For any subsequent authority application beyond the 24 month time mark, confirm that MRD has been detected within the preceding 12 months of this subsequent authority application. Where MRD has since become undetectable, confirm that PBS-subsidy has not exceeded a further 12 months duration from the date that MRD became undetectable. | Compliance with Authority Required procedures - Streamlined Authority Code 16249 |
| C16252 | P16252 | CN16252 | Dasatinib | Acute lymphoblastic leukaemiaInitial treatmentThe condition must be expressing the Philadelphia chromosome; orThe condition must have the transcript BCR-ABL; ANDPatient must have failed treatment with chemotherapy; ANDPatient must have failed treatment with imatinib; ANDPatient must have failed an allogeneic haemopoeitic stem cell transplantation if applicable.Failure of treatment is defined as either:(i) Failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy and imatinib;(ii) Morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib;(iii) Morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.Patients must have active leukaemia, as defined by presence on current pathology assessments of either morphological infiltration of the bone marrow (greater than 5% lymphoblasts) or cerebrospinal fluid or other sites; OR the presence of cells expressing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow of patients in morphological remission.The authority application must be made in writing and must include:(a) details of the proposed prescription; and(b) a completed Acute Lymphoblastic Leukaemia Dasatinib PBS Authority Application - Supporting Information Form; and(c) a pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript. The date of the relevant pathology report(s) need(s) to be provided. | Compliance with Written Authority Required procedures |

[147] Schedule 4, Part 2, second entry for Variation Code “V15457”

omit from the column headed “Variation Code”: V15457 substitute: V15527

[148] Schedule 5, entry for Abacavir with lamivudine

omit from the column headed “Brand”: Abacavir/Lamivudine Mylan

[149] Schedule 5, omit entries for Acalabrutinib

[150] Schedule 5, entry for Adalimumab in the form Injection 40 mg in 0.4 mL pre-filled pen

insert in the column headed “Brand” after entry for the Brand “Humira”: Hyrimoz

[151] Schedule 5, entries for Atorvastatin

omit from the column headed “Brand” (all instances): NOUMED ATORVASTATIN

[152] Schedule 5, entries for Bisoprolol

omit from the column headed “Brand” (all instances): Cipla Bisoprolol

[153] Schedule 5, entries for Celecoxib

omit from the column headed “Brand” (all instances): NOUMED CELECOXIB

[154] Schedule 5, entries for Dimethyl fumarate

omit from the column headed “Brand” (all instances): Dimethyl Fumarate MSN

[155] Schedule 5, entries for Duloxetine

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Duloxetine | GRP-19918 | Capsule 30 mg (as hydrochloride) | Oral | APO-DuloxetineDuloxecorDuloxetine SandozDuloxetine Sandoz 30DYTREX 30Tixol 30 |
| Duloxetine | GRP-19957 | Capsule 60 mg (as hydrochloride) | Oral | APO-DuloxetineDuloxecorDuloxetine SandozDuloxetine Sandoz 60DYTREX 60Tixol 60 |

[156] Schedule 5, entry for Erlotinib in the form Tablet 150 mg (as hydrochloride)

insert in the column headed “Brand” after entry for the Brand “Erlotinib APOTEX”: ERLOTINIB ARX

[157] Schedule 5, entries for Escitalopram

omit from the column headed “Brand” (all instances): NOUMED ESCITALOPRAM

[158] Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate)

(a) omit from the column headed “Form”: Tablet (enteric coated) 40 mg (as magnesium trihydrate) substitute: Tablet (enteric coated) 40 mg (as magnesium)

(b) omit from the column headed “Brand”: Esomeprazole Mylan

[159] Schedule 5, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate)

(a) omit from the column headed “Form”: Tablet (enteric coated) 20 mg (as magnesium trihydrate) substitute: Tablet (enteric coated) 20 mg (as magnesium)

(b) omit from the column headed “Brand”: Esomeprazole Mylan

[160] Schedule 5, entry for Fingolimod

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fingolimod | GRP-26766 | Capsule 500 micrograms (as hydrochloride) | Oral | AKM FingolimodFingolimod SandozFingolimod SUNFingolimod-TevaFynodGilenyaPharmacor Fingolimod |

[161] Schedule 5, entry for Fluoxetine

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fluoxetine | GRP-24550 | Capsule 20 mg (as hydrochloride) | Oral | APO-FluoxetineBlooms the Chemist FluoxetineFLUOTEXFluoxetine APOTEXFluoxetine generichealthFluoxetine SandozZactin |

[162] Schedule 5, omit entry for Hypromellose

[163] Schedule 5, entries for Lamotrigine

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Lamotrigine | GRP-19640 | Tablet 200 mg | Oral | APX-LamotrigineLamictalLAMITANLamotrigine GHLAMOTRIGINE-WGRLogemReedos 200Sandoz Lamotrigine |
| Lamotrigine | GRP-19706 | Tablet 100 mg | Oral | APX-LamotrigineLamictalLAMITANLamotrigine GHLAMOTRIGINE-WGRLogemReedos 100Sandoz Lamotrigine |
| Lamotrigine | GRP-19758 | Tablet 50 mg | Oral | APX-LamotrigineLamictalLAMITANLamotrigine GHLAMOTRIGINE-WGRLogemReedos 50Sandoz Lamotrigine |
| Lamotrigine | GRP-19807 | Tablet 25 mg | Oral | APX-LamotrigineLamictalLAMITANLamotrigine GHLAMOTRIGINE-WGRLogemReedos 25Sandoz Lamotrigine |

[164] Schedule 5, entry for Lansoprazole in the form Capsule 30 mg

omit from the column headed “Brand”: NOUMED LANSOPRAZOLE

[165] Schedule 5, entry for Metformin in each of the forms: Tablet containing metformin hydrochloride 850 mg; Tablet containing metformin hydrochloride 500 mg; and Tablet containing metformin hydrochloride 1g

omit from the column headed “Brand”: APX-Metformin substitute: APX-METFORMIN

[166] Schedule 5, entries for Metoprolol

omit from the column headed “Brand” (all instances): NOUMED METOPROLOL

[167] Schedule 5, entry for Mycophenolic acid in the form Capsule containing mycophenolate mofetil 250 mg

omit from the column headed “Brand”: Ceptolate

[168] Schedule 5, omit entries for Nortriptyline

[169] Schedule 5, entries for Ondansetron

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Ondansetron | GRP-15983 | Tablet (orally disintegrating) 4 mg | Oral | APX-Ondansetron ODTOndansetron Mylan ODTOndansetron ODT-DRLAOndansetron ODT LupinOndansetron ODT ViatrisONDANSETRON ODT-WGROndansetron SZ ODTZotren ODT |
| Ondansetron | GRP-15983 | Wafer 4 mg | Oral | Zofran Zydis |
| Ondansetron | GRP-15402 | Tablet (orally disintegrating) 8 mg | Oral | APX-Ondansetron ODTOndansetron Mylan ODTOndansetron ODT-DRLAOndansetron ODT LupinOndansetron ODT ViatrisONDANSETRON ODT-WGROndansetron SZ ODTZotren ODT |
| Ondansetron | GRP-15402 | Wafer 8 mg | Oral | Zofran Zydis |
| Ondansetron | GRP-19791 | Tablet 4 mg (as hydrochloride dihydrate) | Oral | APO-OndansetronAPX-OndansetronOndansetron-DRLAOndansetron Mylan TabletsOndansetron SZOndansetron Tablets ViatrisONDANSETRON-WGRZofranZotren 4 |
| Ondansetron | GRP-19626 | Tablet 8 mg (as hydrochloride dihydrate) | Oral | APO-OndansetronAPX-OndansetronOndansetron-DRLAOndansetron Mylan TabletsOndansetron SZOndansetron Tablets ViatrisONDANSETRON-WGRZofranZotren 8 |

[170] Schedule 5, entry for Paracetamol in the form Tablet 500 mg

omit from the column headed “Brand”: Parapane

[171] Schedule 5, entry for Pioglitazone in the form Tablet 15 mg (as hydrochloride) *[GRP-19814]*

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pioglitazone | GRP-19814 | Tablet 15 mg (as hydrochloride) | Oral | ActosAPOTEX-PioglitazoneARX-PIOGLITAZONEVexazone |

[172] Schedule 5, entry for Pioglitazone in the form Tablet 30 mg (as hydrochloride) *[GRP-19943]*

substitute:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Pioglitazone | GRP-19943 | Tablet 30 mg (as hydrochloride) | Oral | ActosAPOTEX-PioglitazoneARX-PIOGLITAZONEVexazone |

[173] Schedule 5, entries for Pregabalin

omit from the column headed “Brand” (all instances): NOUMED PREGABALIN

[174] Schedule 5, omit entry for Quinapril in the form Tablet 20 mg (as hydrochloride)

[175] Schedule 5, omit entry for Quinapril in the form Tablet 10 mg (as hydrochloride)

[176] Schedule 5, entries for Sertraline

omit from the column headed “Brand” (all instances): NOUMED SERTRALINE

[177] Schedule 5, entry for Simvastatin in each of the forms: Tablet 20 mg; Tablet 40 mg; and Tablet 10 mg

omit from the column headed “Brand”: NOUMED SIMVASTATIN

[178] Schedule 5, entry for Sitagliptin with metformin in each of the forms: Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride; Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride; and Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride

insert in the column headed “Brand” after entry for the Brand “Sitagliptin/Metformin Sandoz”: SITAGLO-MET

[179] Schedule 5, entries for Sunitinib

omit from the column headed “Brand” (all instances): Sunitinib MSN

[180] Schedule 5, entry for Telmisartan in the form Tablet 80 mg

omit from the column headed “Brand”: NOUMED TELMISARTAN