

**PB 86 of 2024**

**National Health (Pharmaceutical benefits – early supply) Amendment Instrument 2024
(No. 8)**

*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 subsection 84AAA(2) of the *National Health Act 1953*.

Dated 29 August 2024

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Contents

1 Name 1

2 Commencement 1

3 Authority 1

4 Schedules 1

Schedule 1—Amendments 2

National Health (Pharmaceutical benefits—early supply) Instrument 2015
(PB 120 of 2015). 2

1 Name

1. This instrument is the *National Health (Pharmaceutical benefits – early supply) Amendment Instrument 2024 (No. 8)*.
2. This instrument may also be cited as PB 86 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 September 2024* | *1 September 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Note: This table relates only to the provisions of this instrument as originally made.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 subsection 84AAA(2) 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 (Pharmaceutical benefits—early supply) Instrument 2015 (PB 120 of 2015)*

1. Schedule 1, omit entry for Fosinopril with hydrochlorothiazide
2. Schedule 1, after entry for Metoprolol succinate in the form Tablet 190 mg (controlled release)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Migalastat | Capsule containing 150 mg migalastat hydrochloride (equivalent to 123 mg migalastat) | 20 | 14 | 5 |  |

1. Schedule 1, after entry for Tiotropium in the form Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler) | 20 | 30 | 5 |  |

1. Schedule 2, after entry for Acarbose in the form Tablet 100 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Aclidinium | Powder for oral inhalation in breath actuated device 322 micrograms (as bromide) per dose, 60 doses | 50 | 2 | 5 |  |
| Aclidinium with formoterol | Powder for oral inhalation in breath actuated device containing aclidinium 340 micrograms (as bromide) with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Alogliptin with metformin in the form Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Amantadine | Capsule containing amantadine hydrochloride 100 mg | 50 | 200 | 5 |  |

1. Schedule 2, after entry for Apixaban in the form Tablet 5 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Apomorphine | Injection containing apomorphine hydrochloride hemihydrate 50 mg in 5 mL | 50 | 360 | 5 |  |
|  | Injection containing apomorphine hydrochloride hemihydrate 100 mg in 20 mL | 50 | 180 | 5 |  |
|  | Solution for subcutaneous infusion containing apomorphine hydrochloride hemihydrate 50 mg in 10 mL pre-filled syringe | 50 | 360 | 5 |  |
|  | Solution for subcutaneous injection containing apomorphine hydrochloride 30 mg in 3 mL pre-filled pen | 50 | 200 | 5 |  |

1. Schedule 2, after entry for Balsalazide

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Beclometasone | Pressurised inhalation containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing beclometasone dipropionate 100 micrograms per dose, 200 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation in breath actuated device containing beclometasone dipropionate 50 micrograms per dose, 200 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation in breath actuated device containing beclometasone dipropionate 100 micrograms per dose, 200 doses (CFC-free formulation) | 50 | 2 | 5 |  |
| Beclometasone with formoterol | Pressurised inhalation containing beclometasone dipropionate 100 micrograms and formoterol fumarate dihydrate 6 micrograms per dose,120 dose | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing beclometasone dipropionate 200 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 50 | 2 | 5 |  |
| Beclometasone with formoterol and glycopyrronium | Pressurised inhalation containing beclometasone dipropionate 100 micrograms with formoterol fumarate dihydrate 6 micrograms and glycopyrronium 10 micrograms (as bromide) per dose, 120 doses | 50 | 2 | 5 |  |
| Betaxolol | Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL | 50 | 2 | 5 |  |
| Bimatoprost | Eye drops 300 micrograms per mL, 3 mL | 50 | 2 | 5 |  |
|  | Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30 | 50 | 2 | 5 |  |
| Bimatoprost with timolol | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, 3 mL | 50 | 2 | 5 |  |
|  | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30 | 50 | 2 | 5 |  |
| Bisacodyl | Suppositories 10 mg, 10 | 50 | 6 | 5 |  |
|  | Suppositories 10 mg, 12 | 50 | 6 | 4 |  |
|  | Tablet 5 mg | 50 | 400 | 2 |  |

1. Schedule 2, after entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 10 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Brimonidine | Eye drops containing brimonidine tartrate 1.5 mg per mL, 5 mL | 50 | 2 | 5 |  |
|  | Eye drops containing brimonidine tartrate 2 mg per mL, 5 mL | 50 | 2 | 5 |  |
| Brimonidine with timolol | Eye drops containing brimonidine tartrate 2 mg with timolol 5 mg (as maleate) per mL, 5 mL | 50 | 2 | 5 |  |
| Brinzolamide | Eye drops 10 mg per mL, 5 mL | 50 | 2 | 5 |  |
| Brinzolamide with brimonidine | Eye drops 10 mg brinzolamide with 2 mg brimonidine tartrate per mL, 5 mL | 50 | 2 | 5 |  |
| Brinzolamide with timolol | Eye drops 10 mg brinzolamide with timolol 5 mg (as maleate) per mL, 5 mL | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Bromocriptine

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Budesonide | Nebuliser suspension 1 mg in 2 mL single dose units, 30 | 50 | 2 | 5 |  |
|  | Nebuliser suspension 500 micrograms in 2 mL single dose units, 30 | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device 100 micrograms per dose, 200 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device 200 micrograms per dose, 200 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device 400 micrograms per dose, 200 doses | 50 | 2 | 5 |  |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 100 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 50 | 4 | 5 |  |
|  | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | 50 | 4 | 5 |  |
|  | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | 50 | 4 | 5 |  |
| Budesonide with glycopyrronium and formoterol | Pressurised inhalation containing budesonide 160 micrograms with glycopyrronium 7.2 micrograms and formoterol fumarate dihydrate 5 micrograms per dose, 120 doses | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Cabergoline

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Tablet 1 mg | 50 | 60 | 5 |  |
|  | Tablet 2 mg | 50 | 60 | 5 |  |

1. Schedule 2, after entry for Carbamazepine in the form Oral suspension 100 mg per 5 mL, 300 mL

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Tablet 100 mg | 50 | 400 | 2 |  |
|  | Tablet 200 mg | 50 | 400 | 2 |  |

1. Schedule 2, after entry for Carbimazole

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Carbomer | Eye gel 2 mg per g, 10 g | 50 | 2 | 5 |  |
|  | Eye gel 2 mg per g, single dose units 0.6 mL, 30 | 50 | 6 | 5 |  |
| Carmellose | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30 | 50 | 6 | 5 |  |
|  | Eye drops containing carmellose sodium 5 mg per mL, 10 mL | 50 | 2 | 5 |  |
|  | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30 | 50 | 6 | 5 |  |

1. Schedule 2, after entry for Chlortalidone

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ciclesonide | Pressurised inhalation 80 micrograms per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation 160 micrograms per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Ciclosporin in the form Oral liquid 100 mg per mL, 50 mL

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Citalopram | Tablet 10 mg (as hydrobromide) | 50 | 56 | 2 |  |
|  | Tablet 20 mg (as hydrobromide) | 50 | 56 | 2 |  |
|  | Tablet 40 mg (as hydrobromide) | 50 | 56 | 2 |  |

1. Schedule 2, after entry for Clopidogrel with aspirin

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Colestyramine | Sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50 | 50 | 4 | 5 |  |

1. Schedule 2, after entry for Desmopressin in the form Wafer 240 micrograms (as acetate)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Desvenlafaxine | Tablet (extended release) 100 mg (as succinate) | 50 | 56 | 2 |  |
|  | Tablet (extended release) 50 mg (as succinate) | 50 | 56 | 2 |  |
|  | Tablet (modified release) 100 mg | 50 | 56 | 2 |  |
|  | Tablet (modified release) 100 mg (as benzoate) | 50 | 56 | 2 |  |
|  | Tablet (modified release) 50 mg | 50 | 56 | 2 |  |
|  | Tablet (modified release) 50 mg (as benzoate) | 50 | 56 | 2 |  |

1. Schedule 2, after entry for Dexamethasone

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Diltiazem | Capsule (controlled delivery) containing diltiazem hydrochloride 180 mg | 50 | 60 | 5 |  |
|  | Capsule (controlled delivery) containing diltiazem hydrochloride 240 mg | 50 | 60 | 5 |  |
|  | Capsule (controlled delivery) containing diltiazem hydrochloride 360 mg | 50 | 60 | 5 |  |
|  | Tablet containing diltiazem hydrochloride 60 mg | 50 | 180 | 5 |  |
| Dorzolamide | Eye drops 20 mg (as hydrochloride) per mL, 5 mL | 50 | 2 | 5 |  |
| Dorzolamide with timolol | Eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL | 50 | 2 | 5 |  |
| Doxycycline | Capsule 100 mg (as hyclate) (containing enteric coated pellets) | 50 | 56 | 2 |  |
|  | Capsule 50 mg (as hyclate) (containing enteric coated pellets) | 50 | 50 | 2 |  |
|  | Tablet 100 mg (as hyclate) | 50 | 56 | 2 |  |
|  | Tablet 100 mg (as monohydrate) | 50 | 56 | 2 |  |
|  | Tablet 50 mg (as hyclate) | 50 | 50 | 2 |  |
|  | Tablet 50 mg (as monohydrate) | 50 | 50 | 2 |  |

1. Schedule 2, after entry for Enalapril with hydrochlorothiazide

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Entacapone | Tablet 200 mg | 50 | 400 | 4 |  |

1. Schedule 2, after entry for Eprosartan

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Eprosartan with hydrochlorothiazide | Tablet 600 mg eprosartan (as mesilate) with 12.5 mg hydrochlorothiazide | 50 | 56 | 5 |  |
| Erythromycin | Capsule 250 mg (containing enteric coated pellets) | 50 | 100 | 2 |  |
| Escitalopram | Oral solution 20 mg (as oxalate) per mL, 15 mL | 50 | 2 | 2 |  |
|  | Tablet 10 mg (as oxalate) | 50 | 56 | 2 |  |
|  | Tablet 20 mg (as oxalate) | 50 | 56 | 2 |  |
| Esomeprazole | Capsule (enteric) 20 mg (as magnesium) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
|  | Capsule (enteric) 40 mg (as magnesium) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
|  | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
|  | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |

1. Schedule 2, entry for Estradiol with norethisterone

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Estradiol with norethisterone | Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 | 50 | 2 | 5 |  |
|  | Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Fenofibrate in the form Tablet 145 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Fluoxetine | Capsule 20 mg (as hydrochloride) | 50 | 56 | 2 |  |
| Fluticasone furoate | Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms per dose, 30 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms per dose, 30 doses | 50 | 2 | 5 |  |
| Fluticasone furoate with umeclidinium and vilanterol | Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with umeclidinium 62.5 micrograms (as bromide) and vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 50 | 2 | 5 |  |
| Fluticasone furoate with vilanterol | Powder for oral inhalation in breath actuated device containing fluticasone furoate 100 micrograms with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone furoate 200 micrograms with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 50 | 2 | 5 |  |
| Fluticasone propionate | Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 125 micrograms per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |
| Fluticasone propionate with formoterol | Pressurised inhalation containing fluticasone propionate 125 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 250 micrograms with formoterol fumarate dihydrate 10 micrograms per dose, 120 doses | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 50 micrograms with formoterol fumarate dihydrate 5 micrograms per dose, 120 doses | 50 | 2 | 5 |  |
| Fluticasone propionate with salmeterol | Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |
|  | Pressurised inhalation containing fluticasone propionate 50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Fluvastatin

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Fluvoxamine | Tablet containing fluvoxamine maleate 100 mg | 50 | 60 | 2 |  |
|  | Tablet containing fluvoxamine maleate 50 mg | 50 | 60 | 2 |  |
| Formoterol | Capsule containing powder for oral inhalation containing formoterol fumarate dihydrate 12 micrograms (for use in Foradile Aerolizer) | 50 | 120 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 50 | 2 | 5 |  |
|  | Powder for oral inhalation in breath actuated device containing formoterol fumarate dihydrate 6 micrograms per dose, 60 doses | 50 | 2 | 5 |  |

1. Schedule 2, entry for Glyceryl trinitrate

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Glyceryl trinitrate | Sublingual spray (pump pack) 400 micrograms per dose, 200 doses | 50 | 2 | 5 |  |
|  | Transdermal patch 18 mg | 50 | 60 | 5 |  |
|  | Transdermal patch 25 mg | 50 | 60 | 5 |  |
|  | Transdermal patch 36 mg | 50 | 60 | 5 |  |
|  | Transdermal patch 50 mg | 50 | 60 | 5 |  |
|  | Transdermal patch 54 mg | 50 | 60 | 5 |  |

1. Schedule 2, after entry for Glyceryl trinitrate in the form Transdermal patch 54 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Glycopyrronium | Capsule containing powder for oral inhalation 50 micrograms (as bromide) (for use in Breezhaler) | 50 | 60 | 5 |  |
| Hyaluronic acid | Eye drops containing sodium hyaluronate 1 mg per mL, 10 mL | 50 | 2 | 5 |  |
|  | Eye drops containing sodium hyaluronate 2 mg per mL, 10 mL | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Hydrocortisone

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Tablet 20 mg | 50 | 120 | 4 |  |

1. Schedule 2, after entry for Hydrocortisone in the form Tablet 20 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Hypromellose | 0.3% w/v eye drops, 10 mL (preservative free) | 50 | 2 | 5 |  |
|  | Eye drops 3 mg per mL, 10 mL | 50 | 2 | 5 |  |
|  | Eye drops 5 mg per mL, 15 mL | 50 | 2 | 5 |  |
| Hypromellose with dextran | Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL | 50 | 2 | 5 |  |
| Indacaterol | Capsule containing powder for oral inhalation 150 micrograms (as maleate) (for use in Breezhaler) | 50 | 60 | 5 |  |
|  | Capsule containing powder for oral inhalation 300 micrograms (as maleate) (for use in Breezhaler) | 50 | 60 | 5 |  |
| Indacaterol with glycopyrronium | Capsule containing powder for oral inhalation indacaterol 110 micrograms (as maleate) with glycopyrronium 50 micrograms (as bromide) (for use in Breezhaler) | 50 | 60 | 5 |  |
| Indacaterol with glycopyrronium and mometasone | Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 136 micrograms (for use in Breezhaler) | 50 | 60 | 5 |  |
|  | Capsule containing powder for oral inhalation indacaterol 114 micrograms (as maleate) with glycopyrronium 46 micrograms (as bromide) and mometasone furoate 68 micrograms (for use in Breezhaler) | 50 | 60 | 5 |  |
| Indacaterol with mometasone | Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 127.5 micrograms (for use in Breezhaler) | 50 | 60 | 5 |  |
|  | Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 260 micrograms (for use in Breezhaler) | 50 | 60 | 5 |  |
|  | Capsule containing powder for oral inhalation indacaterol 125 micrograms (as acetate) with mometasone furoate 62.5 micrograms (for use in Breezhaler) | 50 | 60 | 5 |  |

1. Schedule 2, after entry for Lamotrigine in the form Tablet 200 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Lansoprazole | Capsule 15 mg | 50 | 60 | 5 |  |
|  | Capsule 30 mg | 50 | 56 | 5 |  |
|  |  | 50 | 112 | 5 |  |
|  | Tablet 15 mg (orally disintegrating) | 50 | 56 | 5 |  |
|  | Tablet 30 mg (orally disintegrating) | 50 | 56 | 5 |  |
|  |  | 50 | 112 | 5 |  |

1. Schedule 2, after entry for Lanthanum in the form Tablet, chewable, 1000 mg (as carbonate hydrate)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Latanoprost | Eye drops 50 micrograms per mL, 2.5 mL | 50 | 2 | 5 |  |
| Latanoprost with timolol | Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Levetiracetam in the form Tablet 1 g

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Levodopa with benserazide | Capsule containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
|  | Capsule containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) (sustained release) | 50 | 200 | 5 |  |
|  | Capsule containing levodopa 50 mg with 12.5 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
|  | Capsule containing levodopa 200 mg with 50 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
|  | Dispersible tablet containing levodopa 50 mg with 12.5 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
|  | Dispersible tablet containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
|  | Tablet containing levodopa 100 mg with 25 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
|  | Tablet containing levodopa 200 mg with 50 mg benserazide (as hydrochloride) | 50 | 200 | 5 |  |
| Levodopa with carbidopa | Tablet (modified release) 200 mg-50 mg (as monohydrate) | 50 | 200 | 5 |  |
|  | Tablet 100 mg-25 mg (as monohydrate) | 50 | 200 | 5 |  |
|  | Tablet 250 mg-25 mg (as monohydrate) | 50 | 200 | 5 |  |
| Levodopa with carbidopa and entacapone | Tablet 50 mg-12.5 mg (as monohydrate)-200 mg | 50 | 400 | 4 |  |
|  | Tablet 75 mg-18.75 mg (as monohydrate)-200 mg | 50 | 400 | 4 |  |
|  | Tablet 100 mg-25 mg (as monohydrate)-200 mg | 50 | 400 | 4 |  |
|  | Tablet 125 mg-31.25 mg (as monohydrate)-200 mg | 50 | 400 | 4 |  |
|  | Tablet 150 mg-37.5 mg (as monohydrate)-200 mg | 50 | 400 | 4 |  |
|  | Tablet 200 mg-50 mg (as monohydrate)-200 mg | 50 | 400 | 4 |  |

1. Schedule 2, after entry for Lisinopril in the form Tablet 20 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Macrogol 3350 | Powder for oral solution 510 g | 50 | 2 | 5 |  |
|  | Sachets containing powder for oral solution 13.125 g with electrolytes, 30 | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Metoprolol succinate in the form Tablet 190 mg (controlled release)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Mianserin | Tablet containing mianserin hydrochloride 10 mg | 50 | 100 | 2 |  |
|  | Tablet containing mianserin hydrochloride 20 mg | 50 | 100 | 2 |  |
| Minocycline | Tablet 50 mg (as hydrochloride) | 50 | 120 | 2 |  |

1. Schedule 2, after entry for Minoxidil

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Mirtazapine | Tablet 15 mg | 50 | 60 | 2 |  |
|  | Tablet 15 mg (orally disintegrating) | 50 | 60 | 2 |  |
|  | Tablet 30 mg | 50 | 60 | 2 |  |
|  | Tablet 30 mg (orally disintegrating) | 50 | 60 | 2 |  |
|  | Tablet 45 mg | 50 | 60 | 2 |  |
|  | Tablet 45 mg (orally disintegrating) | 50 | 60 | 2 |  |
| Moclobemide | Tablet 150 mg | 50 | 120 | 2 |  |
|  | Tablet 300 mg | 50 | 120 | 2 |  |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | 50 | 56 | 5 |  |
|  | Tablet, chewable, 5 mg (as sodium) | 50 | 56 | 5 |  |

1. Schedule 2, after entry for Nifedipine in the form Tablet 60 mg (controlled release)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Nizatidine | Capsule 150 mg | 50 | 120 | 5 |  |
|  | Capsule 300 mg | 50 | 60 | 5 |  |

1. Schedule 2, after entry for Olmesartan with hydrochlorothiazide in the form Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Omeprazole | Capsule 20 mg | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
|  | Tablet 10 mg (as magnesium) | 50 | 60 | 5 |  |
|  | Tablet 20 mg | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
|  | Tablet 20 mg (as magnesium) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |

1. Schedule 2, after entry for Oxcarbazepine in the form Oral suspension 60 mg per mL, 250 mL

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Tablet 150 mg | 50 | 200 | 5 |  |

1. Schedule 2, after entry for Pancreatic extract in the form Granules (enteric coated) providing not less than 5,000 BP units of lipase activity per 100 mg, 20 g

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pantoprazole | Sachet containing granules 40 mg (as sodium sesquihydrate) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
|  | Tablet (enteric coated) 20 mg (as sodium sesquihydrate) | 50 | 60 | 5 |  |
|  | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |
| Paraffin | Eye drops containing liquid paraffin, glycerol, tyloxapol, poloxamer-188, trometamol hydrochloride, trometamol, cetalkonium chloride, 10 mL (preservative free) | 50 | 2 | 5 |  |
|  | Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g | 50 | 4 | 5 |  |
|  | Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g | 50 | 2 | 5 |  |
| Paroxetine | Tablet 20 mg (as hydrochloride) | 50 | 60 | 2 |  |

1. Schedule 2, after entry for Perampanel in the form Tablet 12 mg (as hemisesquihydrate)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Perfluorohexyloctane | Eye drops, 3 mL | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Phenytoin in the form Tablet 50 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pilocarpine | Eye drops containing pilocarpine hydrochloride 10 mg per mL, 15 mL | 50 | 2 | 5 |  |
|  | Eye drops containing pilocarpine hydrochloride 20 mg per mL, 15 mL | 50 | 2 | 5 |  |
|  | Eye drops containing pilocarpine hydrochloride 40 mg per mL, 15 mL | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Pizotifen

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Polyethylene glycol 400 with propylene glycol | Eye drops 4 mg-3 mg per mL, 15 mL | 50 | 2 | 5 |  |
|  | Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30 | 50 | 4 | 5 |  |

1. Schedule 2, after entry for Potassium chloride with potassium bicarbonate

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pramipexole | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 1.5 mg | 50 | 60 | 5 |  |
|  | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 2.25 mg | 50 | 60 | 5 |  |
|  | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3 mg | 50 | 60 | 5 |  |
|  | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 3.75 mg | 50 | 60 | 5 |  |
|  | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 375 micrograms | 50 | 60 | 5 |  |
|  | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 4.5 mg | 50 | 60 | 5 |  |
|  | Tablet (extended release) containing pramipexole dihydrochloride monohydrate 750 micrograms | 50 | 60 | 5 |  |
|  | Tablet containing pramipexole dihydrochloride monohydrate 1 mg | 50 | 200 | 5 |  |
|  | Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms | 50 | 200 | 5 |  |

1. Schedule 2, after entry for Propylthiouracil

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pyridostigmine | Tablet containing pyridostigmine bromide 10 mg | 50 | 200 | 5 |  |
|  | Tablet containing pyridostigmine bromide 180 mg (modified release) | 50 | 200 | 5 |  |
|  | Tablet containing pyridostigmine bromide 60 mg | 50 | 300 | 5 |  |

1. Schedule 2, after entry for Quinagolide

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Rabeprazole | Tablet containing rabeprazole sodium 10 mg (enteric coated) | 50 | 56 | 5 |  |
|  | Tablet containing rabeprazole sodium 20 mg (enteric coated) | 50 | 60 | 5 |  |
|  |  | 50 | 120 | 5 |  |

1. Schedule 2, after entry for Ramipril with felodipine in the form Tablet 5 mg-5 mg (modified release)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Rasagiline | Tablet 1 mg (as mesilate) | 50 | 60 | 5 |  |
| Reboxetine | Tablet 4 mg (as mesilate) | 50 | 120 | 2 |  |
| Riluzole | Oral suspension 50 mg per 10 mL, 300 mL | 50 | 4 | 5 |  |
|  | Tablet 50 mg | 50 | 112 | 5 |  |

1. Schedule 2, after entry for Rosuvastatin in the form Tablet 40 mg (as calcium)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Rotigotine | Transdermal patch 4.5 mg | 50 | 56 | 5 |  |
|  | Transdermal patch 9 mg | 50 | 56 | 5 |  |
|  | Transdermal patch 13.5 mg | 50 | 56 | 5 |  |
|  | Transdermal patch 18 mg | 50 | 56 | 5 |  |

1. Schedule 2, after entry for Sacubitril with valsartan in the form Tablet containing sacubitril 97.2 mg with valsartan 102.8 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Safinamide | Tablet 50 mg | 50 | 60 | 5 |  |
|  | Tablet 100 mg | 50 | 60 | 5 |  |
| Salmeterol | Powder for oral inhalation in breath actuated device 50 micrograms (as xinafoate) per dose, 60 doses | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Saxagliptin with metformin in the form Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Selegiline | Tablet containing selegiline hydrochloride 5 mg | 50 | 200 | 5 |  |
| Sertraline | Tablet 50 mg (as hydrochloride) | 50 | 60 | 2 |  |
|  | Tablet 100 mg (as hydrochloride) | 50 | 60 | 2 |  |

1. Schedule 2, after entry for Sodium bicarbonate

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Sorbitol with sodium citrate dihydrate and sodium lauryl sulfoacetate | Enemas 3.125 g-450 mg-45 mg in 5 mL, 12 | 50 | 4 | 2 |  |
| Soy lecithin | Eye spray 10 mg per mL, 10 mL | 50 | 4 | 5 |  |

1. Schedule 2, after entry for Telmisartan with hydrochlorothiazide in the form Tablet 80 mg-25 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Teriparatide | Injection 250 micrograms per mL, 2.4 mL in multi‑dose pre‑filled pen | 50 | 2 | 2 |  |

1. Schedule 2, entry for Testosterone

*insert as first entry:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Transdermal cream 50 mg per mL, 50 mL | 50 | 2 | 1 |  |

1. Schedule 2, after entry for Testosterone in the form Transdermal gel (pump pack) 23 mg per 1.15 g dose, 56 doses

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Tetrabenazine | Tablet 25 mg | 50 | 224 | 5 |  |

1. Schedule 2, after entry for Ticagrelor

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Tiotropium | Capsule containing powder for oral inhalation 13 micrograms (as bromide) (for use in Zonda device) | 50 | 60 | 5 |  |
|  | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in HandiHaler) | 50 | 60 | 5 |  |
|  | Capsule containing powder for oral inhalation 18 micrograms (as bromide monohydrate) (for use in LupinHaler) | 50 | 60 | 5 |  |
|  | Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) | 50 | 2 | 5 |  |
| Tiotropium with olodaterol | Solution for oral inhalation containing tiotropium 2.5 micrograms (as bromide monohydrate) with olodaterol 2.5 micrograms (as hydrochloride) per dose, 60 doses | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Trandolapril with verapamil in the form Tablet containing trandolapril 4 mg with verapamil hydrochloride 240 mg (sustained release)

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Tranylcypromine | Tablet 10 mg (as sulfate) | 50 | 100 | 1 |  |
| Travoprost | Eye drops 40 micrograms per mL, 2.5 mL | 50 | 2 | 5 |  |
| Travoprost with timolol | Eye drops 40 micrograms travoprost with timolol 5 mg (as maleate) per mL, 2.5 mL | 50 | 2 | 5 |  |
| Umeclidinium | Powder for oral inhalation in breath actuated device 62.5 micrograms (as bromide) per dose, 30 doses | 50 | 2 | 5 |  |
| Umeclidinium with vilanterol | Powder for oral inhalation in breath actuated device containing umeclidinium 62.5 micrograms (as bromide) with vilanterol 25 micrograms (as trifenatate) per dose, 30 doses | 50 | 2 | 5 |  |

1. Schedule 2, after entry for Valsartan with hydrochlorothiazide in the form Tablet 320 mg-25 mg

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Venlafaxine | Capsule (modified release) 75 mg (as hydrochloride) | 50 | 56 | 2 |  |
|  | Capsule (modified release) 150 mg (as hydrochloride) | 50 | 56 | 2 |  |