

PB 72 of 2014

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014   
(No. 10)

*National Health Act 1953*

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 23 September 2014

**FELICITY McNEILL**

First Assistant Secretary

Pharmaceutical Benefits Division

Department of Health

1 Name of Instrument

(1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 10)*.

(2) This Instrument may also be cited as PB 72 of 2014.

2 Commencement

This Instrument commences on 1 October 2014.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

1. Schedule 1, entry for Aciclovir in the form Tablet 200 mg *[Maximum Quantity: 90; Number of Repeats: 5]*
   * 1. *omit from the column headed “Purposes” for the brand “Aciclovir 200”:* **P3633**
     2. *omit from the column headed “Purposes” for the brand “Aciclovir GH”:* **P3633**
     3. *omit from the column headed “Purposes” for the brand “Chem mart Aciclovir”:* **P3633**
     4. *omit from the column headed “Purposes” for the brand “Ozvir”:* **P3633**
     5. *omit from the column headed “Purposes” for the brand “Terry White Chemists Aciclovir”:* **P3633**
2. Schedule 1, entry for Aciclovir in the form Tablet 800 mg *[Maximum Quantity: 35; Number of Repeats: 0]*
   * 1. *omit from the column headed “Purposes” for the brand “Aciclovir 800”:* **P3622 P3631**
     2. *omit from the column headed “Purposes” for the brand “GenRx Aciclovir”:***P3622 P3631**
     3. *omit from the column headed “Purposes” for the brand “Zovirax 800 mg”:***P3622 P3631**
3. Schedule 1, entry for Acitretin in each of the forms: Capsule 10 mg; and Capsule 25 mg

*omit from the column headed “Responsible Person” for the brand “Novatin”:* **IA** *substitute:* **TX**

1. Schedule 1, entry for Aclidinium

*omit from the column headed “Form”:* **containing aclidinium bromide 400 micrograms per dose, 60 doses**

*substitute:* **322 micrograms (as bromide) per dose, 60 doses**

1. **Schedule 1, entry for Alendronic Acid**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet 40 mg (as alendronate sodium) | Oral | Fosamax 40 mg | MK | MP NP | C3256 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol**
   * 1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Alendronate plus D3-DRLA | RZ | MP NP | C4070 C4087 C4110 |  | 4 | 5 | 4 |  |  |

* + 1. *insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | FonatPlus | AF | MP NP | C4070 C4087 C4110 |  | 4 | 5 | 4 |  |  |

1. **Schedule 1, entry for Alprazolam in each of the forms: Tablet 1 mg; and Tablet 2 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ralozam | GN | MP NP | C1975 |  | 50 | 2 | 50 |  |  |

1. **Schedule 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besylate); and Tablet 10 mg (as besylate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Amlodipine-GA | UA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Azathioprine in the form Tablet 50 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Imazam | ER | MP NP |  |  | 100 | 5 | 100 |  |  |

1. **Schedule 1, entry for Capecitabine in the form Tablet 150 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Xelabine | QA | MP | C1522 C1614 C1738 C1739 C3509 C3942 |  | 60 | 2 | 60 |  |  |

1. **Schedule 1, entry for Capecitabine in the form Tablet 500 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Xelabine | QA | MP | C1522 C1614 C1738 C1739 C3509 C3942 |  | 120 | 2 | 120 |  |  |

1. Schedule 1, entry for Carbamazepine in the form Tablet 100 mg *[Brand: Carbamazepine Sandoz]*
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | PDP |  |  | 200 | 0 | 200 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | MP NP |  |  | 200 | 2 | 200 |  |  |

1. Schedule 1, entry for Carbamazepine in the form Tablet 200 mg *[Brand: Carbamazepine Sandoz]*
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | PDP |  |  | 200 | 0 | 200 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | MP NP |  |  | 200 | 2 | 200 |  |  |

1. **Schedule 1, entry for Ceftriaxone in the form Powder for injection 2 g (as sodium)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ceftriaxone ICP | PP | MP NP | C1169 C1846 C1847 |  | 5 | 0 | 1 |  |  |

1. **Schedule 1, entry for Doxycycline in the form Tablet 50 mg (as hydrochloride)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxycycline AN | EA | MP NP | C4475 C4529 C4539 |  | 25 | 5 | 25 |  |  |

1. **Schedule 1, entry for Doxycycline in the form Tablet 100 mg (as hydrochloride) *[Maximum Quantity: 7; Number of Repeats: 0]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxycycline AN | EA | PDP |  |  | 7 | 0 | 7 |  |  |

1. **Schedule 1, entry for Doxycycline in the form Tablet 100 mg (as hydrochloride) *[Maximum Quantity: 7; Number of Repeats: 1]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxycycline AN | EA | MP NP |  |  | 7 | 1 | 7 |  |  |

1. **Schedule 1, entry for Doxycycline in the form Tablet 100 mg (as hydrochloride) *[Maximum Quantity: 21; Number of Repeats: 0]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Doxycycline AN | EA | MP NP |  | P4485 | 21 | 0 | 7 |  |  |

1. **Schedule 1, entry for Duloxetine in the form Capsule 30 mg (as hydrochloride)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pharmacor Duloxetine 30 | CR | MP NP | C1211 |  | 28 | 0 | 28 |  |  |

1. **Schedule 1, entry for Duloxetine in the form Capsule 60 mg (as hydrochloride)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pharmacor Duloxetine 60 | CR | MP NP | C1211 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, after entry for Eptifibatide in the form Solution for I.V. infusion 75 mg (as acetate) in 100 mL**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Eribulin | Solution for I.V. injection containing eribulin mesilate 1 mg in 2 mL | Injection | Halaven | EI | MP | C4646 C4649 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. **Schedule 1, entry for Escitalopram in the form Tablet 10 mg (as oxalate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Cilopam-S | ER | MP NP | C1211 |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Maximum Quantity: 30; Number of Repeats: 1]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Esomeprazole GxP | AF | MP NP | C1337 C1629 C2273 C3429 | P2273 | 30 | 1 | 30 |  |  |

1. **Schedule 1, entry for Esomeprazole in the form Tablet (enteric coated) 20 mg (as magnesium trihydrate) *[Maximum Quantity: 30; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Esomeprazole GxP | AF | MP NP | C1337 C1629 C2273 C3429 | P1337 P1629 P3429 | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Maximum Quantity: 30; Number of Repeats: 1]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Esomeprazole GxP | AF | MP NP | C1337 C1628 C3429 | P1628 | 30 | 1 | 30 |  |  |

1. **Schedule 1, entry for Esomeprazole in the form Tablet (enteric coated) 40 mg (as magnesium trihydrate) *[Maximum Quantity: 30; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Esomeprazole GxP | AF | MP NP | C1337 C1628 C3429 | P1337 P3429 | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Fosinopril with Hydrochlorothiazide in the form Tablet containing fosinopril sodium 10 mg with hydrochlorothiazide 12.5 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fosinopril/HCTZ- GA 10/12.5 | GN | MP NP | C4389 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Fosinopril with Hydrochlorothiazide in the form Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fosinopril/HCTZ- GA 20/12.5 | GN | MP NP | C4389 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, after entry for Glucose Indicator—Blood in the form Test strips, 50 (CareSens N)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Test strips, 50 (EasyMate II) | For external use | EasyMate II | WI | MP NP |  |  | 2 | 5 | 1 |  |  |
|  |  |  |  |  | MP |  | P4241 | 2 | 11 | 1 |  |  |

1. **Schedule 1, after entry for Glucose Indicator—Blood in the form Test strips, 100 (Contour)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Test strips, 100 (EasyMate II) | For external use | EasyMate II | WI | MP NP |  |  | 1 | 5 | 1 |  |  |
|  |  |  |  |  | MP |  | P4241 | 1 | 11 | 1 |  |  |

1. **Schedule 1, entry for Lamotrigine in each of the forms: Tablet 25 mg; Tablet 50 mg; Tablet 100 mg; and Tablet 200 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Lamotrigine AN | EA | MP NP | C1426 |  | 56 | 5 | 56 |  |  |

1. **Schedule 1, entry for Macrogol 3350 in the form Sachets containing powder for oral solution 13.125 g with electrolytes, 30   
   *[Maximum Quantity: 1; Number of Repeats: 5]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Macrovic | QA | MP NP See Note 1 | C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2 | P4576 P4577 P4580 P4596 P4601 See Note 2 | 1 See Note 2 | 5 See  Note 2 | 1 |  |  |

1. **Schedule 1, entry for Macrogol 3350 in the form Sachets containing powder for oral solution 13.125 g with electrolytes, 30   
   *[Maximum Quantity: 2; Number of Repeats: 0]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Macrovic | QA | MP NP See Note 1 | C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2 | P4590 See Note 2 | 2 See Note 2 | 0 See  Note 2 | 1 |  |  |

1. **Schedule 1, entry for Macrogol 3350 in the form Sachets containing powder for oral solution 13.125 g with electrolytes, 30   
   *[Maximum Quantity: 2; Number of Repeats: 3]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Macrovic | QA | MP NP See Note 1 | C4576 C4577 C4580 C4590 C4595 C4596 C4601 See Note 2 | P4595 See Note 2 | 2 See Note 2 | 3 See  Note 2 | 1 |  |  |

1. **Schedule 1, entry for Memantine in the form Tablet containing memantine hydrochloride 10 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Memantine generichealth | GQ | MP NP | C4214 C4218 C4221 |  | 56 | 5 | 56 |  |  |

1. **Schedule 1, entry for Memantine in the form Tablet containing memantine hydrochloride 20 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Memantine generichealth | GQ | MP NP | C4214 C4218 C4221 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Methylprednisolone in each of the forms: Cream containing methylprednisolone aceponate 1 mg per g, 15 g; Ointment containing methylprednisolone aceponate 1 mg per g, 15 g; Fatty ointment containing methylprednisolone aceponate 1 mg   
   per g, 15 g; and Lotion containing methylprednisolone aceponate 1 mg per g, 20 g

*omit from the column headed “Responsible Person”:* **CS** *substitute:* **BN**

1. **Schedule 1, entry for Mianserin in the form Tablet containing mianserin hydrochloride 20 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Tolvon | MK | MP NP | C1355 |  | 50 | 5 | 50 |  |  |

1. **Schedule 1, entry for Mirtazapine in the form Tablet 30 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Mirtazapine‑DP | UA | MP NP | C1211 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Moclobemide in the form Tablet 150 mg

*omit from the column headed “Responsible Person” for the brand “Aurorix”:* **VP** *substitute:* **HM**

1. Schedule 1, entry for Moclobemide in the form Tablet 300 mg

*omit from the column headed “Responsible Person” for the brand “Aurorix 300 mg”:* **VP** *substitute:* **HM**

1. **Schedule 1, entry for Oestradiol and Oestradiol with Dydrogesterone**

*insert as first item in the columns in the order indicated:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Pack containing 14 tablets oestradiol 1 mg and 14 tablets oestradiol 1 mg with dydrogesterone 10 mg | Oral | Femoston 1/10 | AB | MP NP |  |  | 1 | 5 | 1 |  |  |

1. **Schedule 1, after entry for Oestradiol and Oestradiol with Norethisterone in the form Pack containing 4 transdermal patches   
   780 micrograms oestradiol (as hemihydrate) and 4 transdermal patches 510 micrograms oestradiol (as hemihydrate) with 4.8 mg norethisterone acetate**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Oestradiol with dydrogesterone | Tablet 1 mg-5 mg | Oral | Femoston-Conti | AB | MP NP |  |  | 28 | 5 | 28 |  |  |

1. **Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sozol | QA | MP NP | C1337 C1476 C1533 |  | 30 | 5 | 30 |  |  |

1. **Schedule 1, omit entry for Polyethylene glycol 400**
2. **Schedule 1, entry for Pramipexole in the form Tablet containing pramipexole hydrochloride 125 micrograms *[Maximum Quantity: 30; Number of Repeats: 0]***

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pramipexole AN | EA | MP NP | C3216 |  | 30 | 0 | 30 |  |  |

1. **Schedule 1, entry for Pramipexole**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing pramipexole hydrochloride 250 micrograms | Oral | Sifrol | BY | MP NP | C3088 C3216 | P3088 | 100 | 2 | 100 |  |  |
|  |  |  |  |  | MP NP | C3088 C3216 | P3216 | 100 | 5 | 100 |  |  |
|  |  |  | Simipex 0.25 | QA | MP NP | C3216 |  | 100 | 5 | 100 |  |  |

*substitute:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Tablet containing pramipexole hydrochloride 250 micrograms | Oral | Sifrol | BY | MP NP | C3088 C3216 | P3088 | 100 | 2 | 100 |  |  |
|  |  |  | Pramipexole AN | EA | MP NP | C3216 |  | 100 | 5 | 100 |  |  |
|  |  |  | Sifrol | BY | MP NP | C3088 C3216 | P3216 | 100 | 5 | 100 |  |  |
|  |  |  | Simipex 0.25 | QA | MP NP | C3216 |  | 100 | 5 | 100 |  |  |

1. **Schedule 1, entry for Pramipexole in the form Tablet containing pramipexole hydrochloride 1 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pramipexole AN | EA | MP NP | C3216 |  | 100 | 5 | 100 |  |  |

1. **Schedule 1, entry for Quetiapine in the form Tablet 25 mg (as fumarate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Kaptan | ER | MP NP | C4385 C4391 C4396 |  | 60 | 0 | 60 |  |  |

1. **Schedule 1, entry for Quetiapine in the form Tablet 100 mg (as fumarate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Kaptan | ER | MP NP | C1589 C2044 C2765 |  | 90 | 5 | 90 |  |  |

1. **Schedule 1, entry for Quetiapine in each of the forms: Tablet 200 mg (as fumarate); and Tablet 300 mg (as fumarate)**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Kaptan | ER | MP NP | C1589 C2044 C2765 |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 10 mg (enteric coated)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabzole | JS | MP NP | C1337 C1533 |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated)
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabzole | JS | MP NP | C1177 C1337 C1533 | P1177 | 30 | 2 | 30 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabzole | JS | MP NP | C1177 C1337 C1533 | P1337 P1533 | 30 | 5 | 30 |  |  |

1. **Schedule 1, entry for Riluzole in the form Tablet 50 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pharmacor Riluzole | CR | MP NP | C1762 C2718 |  | 56 | 5 | 56 |  |  |

1. Schedule 1, entry for Salbutamol
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule containing powder for oral inhalation 200 micrograms (as sulfate) (for use in Ventolin Rotahaler) | Inhalation by mouth | Ventolin Rotacaps | GK | MP NP |  |  | 200 | 5 | 100 |  |  |

* + 1. substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Capsule containing powder for oral inhalation 200 micrograms (as sulfate) (for use in Ventolin Rotahaler) | Inhalation by mouth | Ventolin Rotacaps | GK | MP NP |  |  | 256 | 4 | 128 |  |  |

1. Schedule 1, entry for Salbutamol in the form Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Airomir | IA | MP NP |  |  | 2 | 5 | 1 |  |  |

1. **Schedule 1, entry for Salbutamol in each of the forms: Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30; and Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Salbutamol Actavis | UA | MP NP | C1754 C1755 |  | 2 | 5 | 1 |  |  |

1. Schedule 1, entry for Strontium
   * 1. *omit from the column headed “Authorised Prescriber”:* **NP**
     2. *omit from the column headed “Circumstances”:* **C4123** *substitute:* **C4644**
2. **Schedule 1, entry for Telmisartan in each of the forms: Tablet 40 mg; and Tablet 80 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Telmisartan RBX | RA | MP NP |  |  | 28 | 5 | 28 |  |  |

1. Schedule 1, entry for Terbinafine in the form Tablet 250 mg (as hydrochloride)
2. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Terbinafine‑GA | UA | MP NP | C2191 C2865 C3244 | P2865 P3244 | 42 | 0 | 42 |  |  |

1. *omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Terbinafine‑GA | UA | MP NP | C2191 C2865 C3244 | P2191 | 42 | 1 | 42 |  |  |

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

*omit from the column headed “Responsible Person”:* **BN** *substitute:* **HB**

1. **Schedule 1, entry for Topiramate in each of the forms: Tablet 25 mg; and Tablet 50 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Topiramate-GA | GN | MP NP | C2797 C2799 |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, entry for Topiramate in each of the forms: Tablet 100 mg; and Tablet 200 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Topiramate-GA | GN | MP NP | C2797 |  | 60 | 5 | 60 |  |  |

1. **Schedule 1, entry for Tramadol in each of the forms: Tablet (sustained release) containing tramadol hydrochloride 100 mg; Tablet (sustained release) containing tramadol hydrochloride 150 mg; and Tablet (sustained release) containing tramadol hydrochloride 200 mg**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Tramadol AN SR | EA | MP NP | C1537 |  | 20 | 0 | 20 |  |  |

1. Schedule 1, entry for Varenicline in the form Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack

*omit from the column headed “Circumstances”:* **C2774 C2775** *substitute:* **C4645**

1. Schedule 1, entry for Varenicline in the form Tablet 1 mg (as tartrate) *[Maximum Quantity: 56; Number of Repeats: 2]*
   * 1. *omit from the column headed “Circumstances”:* **C3670 C3671** *substitute:* **C4647 C4648**
     2. *omit from the column headed “Purposes”:* **P3671** *substitute:* **P4647**
2. Schedule 1, entry for Varenicline in the form Tablet 1 mg (as tartrate) *[Maximum Quantity: 112; Number of Repeats: 0]*
   * 1. *omit from the column headed “Circumstances”:* **C3670 C3671** *substitute:* **C4647 C4648**
     2. *omit from the column headed “Purposes”:* **P3670** *substitute:* **P4648**
3. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| AO | AMO Australia Pty Limited | 95 099 963 194 |

1. Schedule 3, after details relevant to Responsible Person code EH

insert:

|  |  |  |
| --- | --- | --- |
| EI | Eisai Australia Pty Ltd | 73 117 970 993 |

1. Schedule 3, after details relevant to Responsible Person code GZ

insert:

|  |  |  |
| --- | --- | --- |
| HB | Besins Healthcare Australia Pty Ltd | 68 164 882 062 |

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| JS | Janssen‑Cilag Pty Ltd | 47 000 129 975 |

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| VP | Meda Valeant Pharma Australia Pty Ltd | 61 140 839 658 |

1. Schedule 3, after details relevant to Responsible Person code WA

insert:

|  |  |  |
| --- | --- | --- |
| WI | Wincot Pty. Limited | 14 003 526 930 |

1. Schedule 4, Part 1, entry for Alendronic Acid

omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C3256 |  |  | Symptomatic Paget disease of bone | Compliance with Authority Required procedures – Streamlined Authority Code 3256 |

1. Schedule 4, Part 1, after entry for Eptifibatide

insert:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Eribulin | C4646 |  |  | Where the patient is receiving treatment in the community setting or at/from a Private Hospital  Locally advanced or metastatic breast cancer  Patient must have progressive disease; AND Patient must have failed at least two prior chemotherapeutic regimens for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition | Compliance with Authority Required procedures |
|  | C4649 |  |  | Where the patient is receiving treatment at/from a Public Hospital  Locally advanced or metastatic breast cancer  Patient must have progressive disease; AND Patient must have failed at least two prior chemotherapeutic regimens for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition | Compliance with Authority Required procedures - Streamlined Authority Code 4649 |

1. Schedule 4, Part 1, entry for Polyethylene glycol 400
2. Schedule 4, Part 1, entry for Strontium

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Strontium | C4644 |  |  | Severe established osteoporosis  Patient must have fracture due to minimal trauma; AND Patient must not receive concomitant treatment with any other PBS-subsidised anti-resorptive agent for this condition; AND Patient must be at high risk of fracture; AND Patient must be unable to use other medications for the treatment of osteoporosis due to contraindications or intolerance  The fracture must have been demonstrated radiologically and the year of plain x-ray or computed tomography (CT) scan or magnetic resonance imaging (MRI) scan must be documented in the patient's medical records when treatment is initiated  A vertebral fracture is defined as a 20% or greater reduction in height of the anterior or mid portion of a vertebral body relative to the posterior height of that body, or, a 20% or greater reduction in any of these heights compared to the vertebral body above or below the affected vertebral body | Compliance with Authority Required procedures |

1. Schedule 4, Part 1, entry for Varenicline

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Varenicline | C4645 |  |  | Nicotine dependence  Commencement of a short-term (12 weeks or 24 weeks) course of treatment  The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have indicated they are ready to cease smoking  Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program or is about to enter such a program at the time the Authority application is requested  Details of the support and counselling program must be documented in the patient's medical records at the time treatment is initiated  Clinical review is recommended within 2 to 3 weeks of the initial prescription being requested | Compliance with Authority Required procedures |
|  | C4647 | P4647 |  | Nicotine dependence  Completion of a short-term (24 weeks) course of treatment  The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug during this current course of treatment; AND Patient must have ceased smoking following an initial 12-weeks of PBS-subsidised treatment with this drug in the current course of treatment  Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program | Compliance with Authority Required procedures |
|  | C4648 | P4648 |  | Nicotine dependence  Continuation of a short-term (12 weeks or 24 weeks) course of treatment  The treatment must be as an aid to achieving abstinence from smoking; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously been issued with an authority prescription for this drug during this current course of treatment  Patient must be undergoing concurrent counselling for smoking cessation through a comprehensive support and counselling program | Compliance with Authority Required procedures |