**EXPLANATORY STATEMENT**

*National Health Act 1953*

***National Health (Pharmaceutical benefits - early supply) Instrument 2015***

**PB 120 of 2015**

**Authority**

Subsection 84AAA(2) of the *National Health Act 1953* (the Act) provides that in relation to early supply of a pharmaceutical benefit the Minister may specify, by legislative instrument, pharmaceutical items for the purposes of paragraph 84AAA(1)(a) and periods following a previous supply for paragraph 84AAA(1)(b) of the Act.

**Purpose**

The purpose of this legislative instrument is to specify the pharmaceutical items that are in pharmaceutical benefits for which Pharmaceutical Benefits Scheme (PBS) safety net entitlements will not apply for early supplies, and to specify the period following previous supply.

This legislative instrument revokes and replaces the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 – specification under subsection 84AAA(2)* (PB 30 of 2009) to reflect a change to the Act made by the *National Health Amendment (Pharmaceutical Benefits) Act 2015* (the Amending Act), commencing 1 January 2016. The Amending Act is part of the PBS Access and Sustainability Package.

The change to the Act requires the Minister to specify the early supply period. In this instrument, the period specified is 20 days in all cases, which aligns with the 20 day period previously required by the Act. The instrument also adds pharmaceutical items containing 141 drugs to early supply, as well as making a number of alterations and deletions.

Subsection 84AAA(1) of the Act provides that a supply of a pharmaceutical benefit to a person is an early supply if the pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection 84AAA(2) and the supply is made within the period specified (currently 20 days) following a previous supply to the person of the same pharmaceutical benefit, or another pharmaceutical benefit that has the same pharmaceutical item, or another pharmaceutical benefit that is Schedule equivalent.

If an ‘early supply’ of a pharmaceutical benefit occurs, the patient contribution for the early supply does not count towards the PBS safety net threshold, and, if the PBS safety net threshold is passed and PBS safety net would normally allow a concessional or nil contribution, the patient contribution and payments to approved suppliers revert, for that early supply, to pre-PBS safety net amounts.

Early supply does not apply to supplies on prescriptions originating in a hospital, or, supplies of out-patient medication by public hospitals. PBS safety net, including early supply, applies to the Repatriation Pharmaceutical Benefits Scheme (RPBS).

The Pharmaceutical Benefits Advisory Committee (PBAC) has made recommendations to the Minister about what should be specified in this early supply instrument.

Attachment 2 summarises in Tables 1, 2, 3, 4 and 5 additions and changes to listed drugs, forms and circumstances effective from 1 January 2016. Items and circumstances in the revoked instrument but not in this Instrument (deletions) are in Table 6.

###### Consultation

The PBS Access and Sustainability Package includes measures relating to the Sixth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia and the Strategic Agreement with the Generic Medicines Industry Association (now known as the Generic and Biosimilar Medicines Association). The measures were negotiated following consultations during the first half of 2015 by the Minister for Health and the Department of Health with stakeholders from the pharmaceutical sector including industry, consumer, medical, pharmacist and wholesaler groups. Organisations represented included Medicines Australia, the Generic Medicines Industry Association, the Consumers Health Forum, NPS MedicineWise, the Australian Medical Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, and the National Pharmaceutical Services Association.

The involvement of PBAC constitutes a formal and ongoing process of consultation. The PBAC is the independent expert body, established by section 100A of the Act, which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the Committee, including the option of appointing an industry member. The PBAC has provided advice regarding what should be specified in this Instrument.

This Instrument commences on 1 January 2016.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

**ATTACHMENT 1**

**Section 1**

This section provides that the name of the Instrument is the *National Health (Pharmaceutical benefits - early supply) Instrument 2015* and that the Instrument may also be cited as No. PB 120 of 2015.

**Section 2**

This section provides that the Instrument commences on 1 January 2016.

**Section 3**

This section provides that the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 - specification under subsection 84AAA(2)*,also referred to asNo. PB 30 of 2009, is revoked.

**Section 4**

This section defines certain terms for the purposes of this determination.

**Section 5**

This section provides that a pharmaceutical item in a pharmaceutical benefit is specified for paragraph 84AAA(1)(a) of the Act if the name of the listed drug and the form of the listed drug are mentioned in Schedule 1 and all the circumstances identified in section 6 (for subsection 84AAA(3) of the Act) as applying to the benefit are satisfied by virtue that they exist in relation to a benefit that has the item.

**Section 6**

This section provides that the circumstances which apply to a pharmaceutical benefit that has a pharmaceutical item are that the form (strength, type, size, etc.) is the same as that determined under subsection 85(3) of the Act, the maximum quantity or number of units is that same as determined under paragraph 85A(2)(a), the maximum number of repeats is that same as determined under paragraph 85A(2)(b), and any other circumstance for paragraph 84AAA(3)(b), all as mentioned in the table in Schedule 1. There are no other circumstances currently specified.

**Section 7**

This section provides that for a pharmaceutical benefit that has the listed drug and form, and the circumstances identified for section 6 in the table in Schedule 1, the number mentioned under the heading ‘Period (days)’ is the period in days for paragraph 84AAA(1)(b) of the Act.

**Schedule 1**

The schedule contains the specified pharmaceutical items, circumstances and periods.

**ATTACHMENT 2**

**Summary of changes from Schedule 1 of PB 30 of 2009**

The changes to Schedule 1 involve additions and deletions to listed drugs and forms, and changes to circumstances, including the maximum quantity or number of units and the maximum number of repeats. The number ‘20’ is included in the column headed ‘Period (days)’ as the period in days for each item.

The listed drug, form, maximum quantity or number of units and maximum number of repeats for a pharmaceutical item are the same as declared and determined under the Act in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), current as at 1 January 2016.

The changes made by this Instrument are summarised below.

**Table 1. Listed drugs added**

| **Listed drug** |
| --- |
| Abiraterone |
| Allopurinol |
| Alogliptin |
| Alogliptin with metformin |
| Aspirin |
| Aurothiomalate |
| Azathioprine |
| Benzhexol |
| Betamethasone |
| Biperiden |
| Bupropion |
| Calcitriol |
| Calcium |
| Carbamazepine |
| Citalopram |
| Clonazepam |
| Colestipol |
| Cyproheptadine |
| Dabrafenib |
| Dapagliflozin |
| Dapagliflozin with metformin |
| Dapsone |
| Dasatinib |
| Denosumab |
| Desmopressin |
| Desvenlafaxine |
| Digoxin |
| Dimethyl fumarate |
| Donepezil |
| Duloxetine |
| Entacapone |
| Erlotinib |
| Escitalopram |
| Esomeprazole and clarithromycin and amoxycillin |
| Ethosuximide |
| Etonogestrel |
| Exenatide |
| Fingolimod |
| Fludrocortisone |
| Fluvoxamine |
| Folic acid |
| Frusemide |
| Gabapentin |
| Galantamine |
| Gestrinone |
| Glatiramer |
| Gliclazide |
| Glimepiride |
| Goserelin |
| Griseofulvin |
| Hydrochlorothiazide |
| Hydrochlorothiazide with amiloride |
| Hydrochlorothiazide with triamterene |
| Hydroxocobalamin |
| Hydroxychloroquine |
| Ibandronic acid |
| Indapamide |
| Insulin aspart |
| Insulin aspart with insulin aspart protamine suspension |
| Insulin detemir |
| Insulin glargine |
| Insulin glulisine |
| Insulin isophane |
| Insulin lispro |
| Insulin lispro with insulin lispro protamine suspension |
| Insulin neutral |
| Insulin neutral with insulin isophane |
| Isotretinoin |
| Ketoprofen |
| Lacosamide |
| Lamotrigine |
| Levetiracetam |
| Levodopa with carbidopa and entacapone |
| Levonorgestrel |
| Levonorgestrel with ethinyloestradiol |
| Linagliptin |
| Linagliptin with metformin |
| Liothyronine |
| Lisdexamfetamine |
| Medroxyprogesterone |
| Megestrol |
| Meloxicam |
| Memantine |
| Metformin |
| Metformin with glibenclamide |
| Methylprednisolone |
| Mirtazapine |
| Moclobemide |
| Montelukast |
| Nafarelin |
| Naproxen |
| Norethisterone |
| Norethisterone with ethinyloestradiol |
| Norethisterone with mestranol |
| Oxcarbazepine |
| Oxybutynin |
| Paracetamol |
| Paroxetine |
| Perampanel |
| Phenobarbitone |
| Phenytoin |
| Pioglitazone |
| Pizotifen |
| Potassium chloride |
| Potassium chloride with potassium bicarbonate |
| Pregabalin |
| Primidone |
| Propantheline |
| Quinagolide |
| Reboxetine |
| Rifaximin |
| Rivastigmine |
| Rosiglitazone |
| Rosiglitazone with metformin |
| Rotigotine |
| Saxagliptin |
| Saxagliptin with metformin |
| Sertraline |
| Sitagliptin |
| Sitagliptin with metformin |
| Sorafenib |
| Sucralfate |
| Sulthiame |
| Sunitinib |
| Tacrolimus |
| Terbinafine |
| Teriflunomide |
| Tetrabenazine |
| Thyroxine |
| Tiagabine |
| Tiludronic acid |
| Topiramate |
| Triamcinolone |
| Ustekinumab |
| Valproic acid |
| Varenicline |
| Venlafaxine |
| Vigabatrin |
| Vildagliptin |
| Vildagliptin with metformin |
| Zonisamide |

**Table 2. Forms for added listed drugs**

| **Listed drug** | **Form** |
| --- | --- |
| Abiraterone | Tablet containing abiraterone acetate 250 mg |
| Allopurinol | Tablet 100 mg |
| Allopurinol | Tablet 300 mg |
| Alogliptin | Tablet 12.5 mg (as benzoate) |
| Alogliptin | Tablet 25 mg (as benzoate) |
| Alogliptin | Tablet 6.25 mg (as benzoate) |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride |
| Aspirin | Tablet 100 mg |
| Aspirin | Tablet, dispersible, 300 mg |
| Aurothiomalate | Injection containing sodium aurothiomalate 20 mg |
| Aurothiomalate | Injection containing sodium aurothiomalate 50 mg |
| Azathioprine | Tablet 25 mg |
| Azathioprine | Tablet 50 mg |
| Benzhexol | Tablet containing benzhexol hydrochloride 2 mg |
| Benzhexol | Tablet containing benzhexol hydrochloride 5 mg |
| Betamethasone | Injection containing betamethasone acetate 3 mg with betamethasone sodium phosphate 3.9 mg in 1 mL |
| Biperiden | Tablet containing biperiden hydrochloride 2 mg |
| Bupropion | Tablet containing bupropion hydrochloride 150 mg (sustained release) |
| Calcitriol | Capsule 0.25 microgram |
| Calcium | Tablet 600 mg (as carbonate) |
| Calcium | Tablet, chewable, 500 mg (as carbonate) |
| Carbamazepine | Tablet 100 mg |
| Carbamazepine | Tablet 200 mg |
| Carbamazepine | Tablet 200 mg (controlled release) |
| Carbamazepine | Tablet 400 mg (controlled release) |
| Citalopram | Tablet 20 mg (as hydrobromide) |
| Citalopram | Tablet 40 mg (as hydrobromide) |
| Clonazepam | Tablet 2 mg |
| Clonazepam | Tablet 500 micrograms |
| Colestipol | Oral powder, sachets containing colestipol hydrochloride 5 g, 120 |
| Cyproheptadine | Tablet containing cyproheptadine hydrochloride 4 mg (anhydrous) |
| Dabrafenib | Capsule 50 mg (as mesilate) |
| Dabrafenib | Capsule 75 mg (as mesilate) |
| Dapagliflozin | Tablet 10 mg (as propanediol monohydrate) |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride |
| Dapagliflozin with metformin | Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride |
| Dapsone | Tablet 100 mg |
| Dapsone | Tablet 25 mg |
| Dasatinib | Tablet 100 mg |
| Dasatinib | Tablet 20 mg |
| Dasatinib | Tablet 50 mg |
| Dasatinib | Tablet 70 mg |
| Denosumab | Injection 60 mg in 1 mL pre-filled syringe |
| Desmopressin | Tablet containing desmopressin acetate 200 micrograms |
| Desmopressin | Wafer 120 micrograms (as acetate) |
| Desmopressin | Wafer 240 micrograms (as acetate) |
| Desvenlafaxine | Tablet (extended release) 100 mg (as succinate) |
| Desvenlafaxine | Tablet (extended release) 50 mg (as succinate) |
| Desvenlafaxine | Tablet (modified release) 100 mg |
| Desvenlafaxine | Tablet (modified release) 100 mg (as benzoate) |
| Desvenlafaxine | Tablet (modified release) 50 mg |
| Desvenlafaxine | Tablet (modified release) 50 mg (as benzoate) |
| Digoxin | Tablet 250 micrograms |
| Digoxin | Tablet 62.5 micrograms |
| Dimethyl fumarate | Capsule (modified release) 240 mg |
| Donepezil | Tablet containing donepezil hydrochloride 10 mg |
| Donepezil | Tablet containing donepezil hydrochloride 5 mg |
| Duloxetine | Capsule 60 mg (as hydrochloride) |
| Entacapone | Tablet 200 mg |
| Erlotinib | Tablet 100 mg (as hydrochloride) |
| Erlotinib | Tablet 150 mg (as hydrochloride) |
| Erlotinib | Tablet 25 mg (as hydrochloride) |
| Escitalopram | Tablet 10 mg (as oxalate) |
| Escitalopram | Tablet 20 mg (as oxalate) |
| Esomeprazole and clarithromycin and amoxycillin | Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg (as trihydrate) |
| Ethosuximide | Capsule 250 mg |
| Etonogestrel | Subcutaneous implant 68 mg |
| Exenatide | Injection solution 10 micrograms per dose in pre-filled pen, 60 doses |
| Exenatide | Injection solution 5 micrograms per dose in pre-filled pen, 60 doses |
| Fingolimod | Capsule 500 micrograms (as hydrochloride) |
| Fludrocortisone | Tablet containing fludrocortisone acetate 100 micrograms |
| Fluvoxamine | Tablet containing fluvoxamine maleate 100 mg |
| Fluvoxamine | Tablet containing fluvoxamine maleate 50 mg |
| Folic acid | Tablet 5 mg |
| Folic acid | Tablet 500 micrograms |
| Frusemide | Tablet 20 mg |
| Frusemide | Tablet 40 mg |
| Gabapentin | Capsule 100 mg |
| Gabapentin | Capsule 300 mg |
| Gabapentin | Capsule 400 mg |
| Gabapentin | Tablet 600 mg |
| Gabapentin | Tablet 800 mg |
| Galantamine | Capsule (prolonged release) 16 mg (as hydrobromide) |
| Galantamine | Capsule (prolonged release) 24 mg (as hydrobromide) |
| Galantamine | Capsule (prolonged release) 8 mg (as hydrobromide) |
| Gestrinone | Capsule 2.5 mg |
| Glatiramer | Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe |
| Gliclazide | Tablet 60 mg (modified release) |
| Gliclazide | Tablet 80 mg |
| Glimepiride | Tablet 3 mg |
| Glimepiride | Tablet 4 mg |
| Goserelin | Subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe |
| Goserelin | Subcutaneous implant 3.6 mg (as acetate) in pre-filled injection syringe |
| Griseofulvin | Tablet 125 mg |
| Hydrochlorothiazide | Tablet 25 mg |
| Hydrochlorothiazide with amiloride | Tablet containing hydrochlorothiazide 50 mg with amiloride hydrochloride 5 mg |
| Hydrochlorothiazide with triamterene | Tablet 25 mg-50 mg |
| Hydroxocobalamin | Injection 1 mg (as acetate) in 1 mL |
| Hydroxocobalamin | Injection 1 mg (as chloride) in 1 mL |
| Hydroxychloroquine | Tablet containing hydroxychloroquine sulfate 200 mg |
| Ibandronic acid | Tablet 50 mg (as ibandronate sodium monohydrate) |
| Indapamide | Tablet containing indapamide hemihydrate 1.5 mg (sustained release) |
| Indapamide | Tablet containing indapamide hemihydrate 2.5 mg |
| Insulin aspart | Injection (human analogue) 100 units per mL, 10 mL vial |
| Insulin aspart | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin aspart with insulin aspart protamine suspension | Injections (human analogue), cartridges, 30 units-70 units per mL, 3 mL, 5 |
| Insulin detemir | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin glargine | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin glulisine | Injection (human analogue) 100 units per mL, 10 mL |
| Insulin glulisine | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin isophane | Injection (bovine) 100 units per mL, 10 mL |
| Insulin isophane | Injection (human) 100 units per mL, 10 mL |
| Insulin isophane | Injections (human), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin lispro | Injection (human analogue) 100 units per mL, 10 mL vial |
| Insulin lispro | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin lispro with insulin lispro protamine suspension | Injections (human analogue), cartridges, 25 units-75 units per mL, 3 mL, 5 |
| Insulin lispro with insulin lispro protamine suspension | Injections (human analogue), cartridges, 50 units-50 units per mL, 3 mL, 5 |
| Insulin neutral | Injection (bovine) 100 units per mL, 10 mL |
| Insulin neutral | Injection (human) 100 units per mL, 10 mL |
| Insulin neutral | Injections (human), cartridges, 100 units per mL, 3 mL, 5 |
| Insulin neutral with insulin isophane | Injection (human) 30 units-70 units per mL, 10 mL |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5 |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 |
| Isotretinoin | Capsule 10 mg |
| Isotretinoin | Capsule 20 mg |
| Isotretinoin | Capsule 40 mg |
| Ketoprofen | Capsule 200 mg (sustained release) |
| Lacosamide | Tablet 100 mg |
| Lacosamide | Tablet 150 mg |
| Lacosamide | Tablet 200 mg |
| Lamotrigine | Tablet 100 mg |
| Lamotrigine | Tablet 200 mg |
| Lamotrigine | Tablet 25 mg |
| Lamotrigine | Tablet 5 mg |
| Lamotrigine | Tablet 50 mg |
| Levetiracetam | Oral solution 100 mg per mL, 300 mL |
| Levetiracetam | Tablet 1 g |
| Levetiracetam | Tablet 250 mg |
| Levetiracetam | Tablet 500 mg |
| Levodopa with carbidopa and entacapone | Tablet 100 mg-25 mg-200 mg |
| Levodopa with carbidopa and entacapone | Tablet 125 mg-31.25 mg-200 mg |
| Levodopa with carbidopa and entacapone | Tablet 150 mg-37.5 mg-200 mg |
| Levodopa with carbidopa and entacapone | Tablet 200 mg-50 mg-200 mg |
| Levodopa with carbidopa and entacapone | Tablet 50 mg-12.5 mg-200 mg |
| Levodopa with carbidopa and entacapone | Tablet 75 mg-18.75 mg-200 mg |
| Levonorgestrel | Intrauterine drug delivery system 52 mg |
| Levonorgestrel | Tablets 30 micrograms, 28 |
| Levonorgestrel with ethinyloestradiol | Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets |
| Levonorgestrel with ethinyloestradiol | Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets |
| Levonorgestrel with ethinyloestradiol | Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets |
| Levonorgestrel with ethinyloestradiol | Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets |
| Linagliptin | Tablet 5 mg |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride |
| Liothyronine | Tablet containing liothyronine sodium 20 micrograms |
| Lisdexamfetamine | Capsule containing lisdexamfetamine dimesilate 50 mg |
| Medroxyprogesterone | Injection containing medroxyprogesterone acetate 150 mg in 1 mL |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 10 mg |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 5 mg |
| Megestrol | Tablet containing megestrol acetate 160 mg |
| Meloxicam | Capsule 15 mg |
| Meloxicam | Tablet 15 mg |
| Memantine | Tablet containing memantine hydrochloride 10 mg |
| Memantine | Tablet containing memantine hydrochloride 20 mg |
| Metformin | Tablet (extended release) containing metformin hydrochloride 1 g |
| Metformin | Tablet (extended release) containing metformin hydrochloride 500 mg |
| Metformin | Tablet containing metformin hydrochloride 1 g |
| Metformin | Tablet containing metformin hydrochloride 500 mg |
| Metformin | Tablet containing metformin hydrochloride 850 mg |
| Metformin with glibenclamide | Tablet containing metformin hydrochloride 250 mg with glibenclamide 1.25 mg |
| Metformin with glibenclamide | Tablet containing metformin hydrochloride 500 mg with glibenclamide 2.5 mg |
| Metformin with glibenclamide | Tablet containing metformin hydrochloride 500 mg with glibenclamide 5 mg |
| Methylprednisolone | Injection containing methylprednisolone acetate 40 mg in 1 mL |
| Mirtazapine | Tablet 45 mg |
| Mirtazapine | Tablet 45 mg (orally disintegrating) |
| Moclobemide | Tablet 150 mg |
| Moclobemide | Tablet 300 mg |
| Montelukast | Tablet, chewable, 4 mg (as sodium) |
| Montelukast | Tablet, chewable, 5 mg (as sodium) |
| Nafarelin | Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses |
| Naproxen | Tablet 1 g (sustained release) |
| Naproxen | Tablet 750 mg (sustained release) |
| Norethisterone | Tablets 350 micrograms, 28 |
| Norethisterone with ethinyloestradiol | Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets |
| Norethisterone with ethinyloestradiol | Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets |
| Norethisterone with mestranol | Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets |
| Oxcarbazepine | Tablet 600 mg |
| Oxybutynin | Tablet containing oxybutynin hydrochloride 5 mg |
| Oxybutynin | Transdermal patches 36 mg, 8 |
| Paracetamol | Tablet 500 mg |
| Paracetamol | Tablet 665 mg (modified release) |
| Paroxetine | Tablet 20 mg (as hydrochloride) |
| Paroxetine | Tablet 20 mg (as mesilate) |
| Perampanel | Tablet 10 mg (as hemisesquihydrate) |
| Perampanel | Tablet 12 mg (as hemisesquihydrate) |
| Perampanel | Tablet 4 mg (as hemisesquihydrate) |
| Perampanel | Tablet 6 mg (as hemisesquihydrate) |
| Perampanel | Tablet 8 mg (as hemisesquihydrate) |
| Phenobarbitone | Tablet 30 mg |
| Phenytoin | Capsule containing phenytoin sodium 100 mg |
| Phenytoin | Capsule containing phenytoin sodium 30 mg |
| Phenytoin | Tablet 50 mg |
| Pioglitazone | Tablet 45 mg (as hydrochloride) |
| Pizotifen | Tablet 500 micrograms (as malate) |
| Potassium chloride | Tablet 600 mg (sustained release) |
| Potassium chloride with potassium bicarbonate | Tablet, effervescent, 14 mmol potassium and 8 mmol chloride |
| Pregabalin | Capsule 300 mg |
| Primidone | Tablet 250 mg |
| Propantheline | Tablet containing propantheline bromide 15 mg |
| Quinagolide | Tablet 75 micrograms (as hydrochloride) |
| Reboxetine | Tablet 4 mg (as mesilate) |
| Rifaximin | Tablet 550 mg |
| Rivastigmine | Capsule 1.5 mg (as hydrogen tartrate) |
| Rivastigmine | Capsule 3 mg (as hydrogen tartrate) |
| Rivastigmine | Capsule 4.5 mg (as hydrogen tartrate) |
| Rivastigmine | Capsule 6 mg (as hydrogen tartrate) |
| Rivastigmine | Transdermal patch 18 mg |
| Rivastigmine | Transdermal patch 27 mg |
| Rivastigmine | Transdermal patch 9 mg |
| Rosiglitazone | Tablet 8 mg (as maleate) |
| Rosiglitazone with metformin | Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride |
| Rosiglitazone with metformin | Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride |
| Rosiglitazone with metformin | Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride |
| Rosiglitazone with metformin | Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride |
| Rotigotine | Transdermal patch 13.5 mg |
| Rotigotine | Transdermal patch 4.5 mg |
| Rotigotine | Transdermal patch 9 mg |
| Saxagliptin | Tablet 2.5 mg (as hydrochloride) |
| Saxagliptin | Tablet 5 mg (as hydrochloride) |
| Saxagliptin with metformin | Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride |
| Sertraline | Tablet 100 mg (as hydrochloride) |
| Sertraline | Tablet 50 mg (as hydrochloride) |
| Sitagliptin | Tablet 100 mg (as phosphate monohydrate) |
| Sitagliptin | Tablet 25 mg (as phosphate monohydrate) |
| Sitagliptin | Tablet 50 mg (as phosphate monohydrate) |
| Sitagliptin with metformin | Tablet (modified release) containing 100 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride |
| Sorafenib | Tablet 200 mg (as tosylate) |
| Sucralfate | Tablet equivalent to 1 g anhydrous sucralfate |
| Sulthiame | Tablet 200 mg |
| Sulthiame | Tablet 50 mg |
| Sunitinib | Capsule 12.5 mg (as malate) |
| Sunitinib | Capsule 25 mg (as malate) |
| Sunitinib | Capsule 37.5 mg (as malate) |
| Sunitinib | Capsule 50 mg (as malate) |
| Tacrolimus | Capsule 0.5 mg (once daily prolonged release) |
| Tacrolimus | Capsule 1 mg (once daily prolonged release) |
| Tacrolimus | Capsule 5 mg (once daily prolonged release) |
| Terbinafine | Tablet 250 mg (as hydrochloride) |
| Teriflunomide | Tablet 14 mg |
| Tetrabenazine | Tablet 25 mg |
| Thyroxine | Tablet containing 100 micrograms anhydrous thyroxine sodium |
| Thyroxine | Tablet containing 200 micrograms anhydrous thyroxine sodium |
| Thyroxine | Tablet containing 50 micrograms anhydrous thyroxine sodium |
| Thyroxine | Tablet containing 75 micrograms anhydrous thyroxine sodium |
| Tiagabine | Tablet 10 mg (as hydrochloride) |
| Tiagabine | Tablet 15 mg (as hydrochloride) |
| Tiagabine | Tablet 5 mg (as hydrochloride) |
| Tiludronic acid | Tablet 200 mg (as tiludronate disodium) |
| Topiramate | Capsule 15 mg |
| Topiramate | Capsule 25 mg |
| Topiramate | Capsule 50 mg |
| Topiramate | Tablet 100 mg |
| Topiramate | Tablet 200 mg |
| Topiramate | Tablet 25 mg |
| Topiramate | Tablet 50 mg |
| Triamcinolone | Injection containing triamcinolone acetonide 10 mg in 1 mL |
| Ustekinumab | Injection 45 mg in 0.5 mL |
| Valproic acid | Tablet (enteric coated) containing sodium valproate 200 mg |
| Valproic acid | Tablet (enteric coated) containing sodium valproate 500 mg |
| Varenicline | 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 |
| Varenicline | Tablet 1 mg (as tartrate) |
| Venlafaxine | Capsule (modified release) 150 mg (as hydrochloride) |
| Venlafaxine | Capsule (modified release) 75 mg (as hydrochloride) |
| Vigabatrin | Oral powder, sachet 500 mg |
| Vigabatrin | Tablet 500 mg |
| Vildagliptin | Tablet 50 mg |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride |
| Zonisamide | Capsule 100 mg |
| Zonisamide | Capsule 25 mg |
| Zonisamide | Capsule 50 mg |

**Table 3. Forms added for listed drugs already included**

| **Listed drug** | **Form** |
| --- | --- |
| Aciclovir | Tablet 800 mg |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen, 6 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe, 6 |
| Dabigatran etexilate | Capsule 75 mg (as mesilate) |
| Degarelix | Powder for injection 120 mg (as acetate), 2, injection set |
| Goserelin and bicalutamide | Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg |
| Goserelin and bicalutamide | Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 84 tablets bicalutamide 50 mg |
| Leuprorelin | I.M. injection (3 month modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe |
| Leuprorelin | I.M. injection (modified release), powder for injection containing leuprorelin acetate 22.5 mg with diluent in pre-filled dual-chamber syringe |
| Leuprorelin | I.M. injection (modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set |
| Oestradiol | Tablet 2 mg |
| Oestradiol | Tablet containing oestradiol valerate 1 mg |
| Oestradiol | Tablet containing oestradiol valerate 2 mg |
| Risedronic acid | Tablet containing risedronate sodium 30 mg |
| Testosterone | I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL |
| Testosterone | Injection containing testosterone enanthate 250 mg in 1 mL |
| Testosterone | Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2 |
| Tiotropium | Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) |
| Triptorelin | Powder for I.M. injection (prolonged release) 11.25 mg (as embonate) with solvent, syringe and needles |
| Triptorelin | Powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles |

**Table 4. Added or amended maximum quantities or maximum repeats**

|  |  |  |  |
| --- | --- | --- | --- |
| **Listed drug** | **Form** | **Maximum quantity** | **Maximum number of repeats** |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | 2 | 0 |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | 2 | 3 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | 2 | 0 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | 2 | 2 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | 2 | 0 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | 2 | 2 |
| Apixaban | Tablet 2.5 mg | 60 | 0 |
| Apixaban | Tablet 5 mg | 28 | 0 |
| Dabigatran etexilate | Capsule 110 mg (as mesilate) | 60 | 0 |
| Esomeprazole | Capsule (enteric) 20 mg (as magnesium) | 30 | 1 |
| Esomeprazole | Capsule (enteric) 40 mg (as magnesium) | 30 | 1 |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | 30 | 1 |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | 30 | 1 |
| Imatinib | Tablet 100 mg (as mesylate) | 60 | 2 |
| Imatinib | Tablet 400 mg (as mesylate) | 30 | 2 |
| Lansoprazole | Capsule 30 mg | 28 | 1 |
| Lansoprazole | Tablet 30 mg (orally disintegrating) | 28 | 1 |
| Omeprazole | Capsule 20 mg | 30 | 1 |
| Omeprazole | Tablet 20 mg | 30 | 1 |
| Omeprazole | Tablet 20 mg (as magnesium) | 30 | 1 |
| Pantoprazole | Sachet containing granules 40 mg (as sodium sesquihydrate) | 30 | 2 |
| Pantoprazole | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | 30 | 2 |
| Pazopanib | Tablet 200 mg (as hydrochloride) | 90 | 2 |
| Pazopanib | Tablet 400 mg (as hydrochloride) | 60 | 2 |
| Rabeprazole | Tablet containing rabeprazole sodium 20 mg (enteric coated) | 30 | 2 |
| Sapropterin | Tablet (soluble) containing sapropterin dihydrochloride 100 mg | 180 | 0 |
| Tamoxifen | Tablet 20 mg (as citrate) | 60 | 5 |
| Temozolomide | Capsule 100 mg | 15 | 2 |
| Temozolomide | Capsule 140 mg | 15 | 2 |
| Temozolomide | Capsule 20 mg | 15 | 2 |
| Temozolomide | Capsule 5 mg | 15 | 2 |

**Table 5. Summary of additions and changes**

| **Listed drug** | **Form** | **Maximum quantity** | **Maximum number of repeats** |
| --- | --- | --- | --- |
| Abiraterone | Tablet containing abiraterone acetate 250 mg | 120 | 2 |
| Aciclovir | Tablet 800 mg | 120 | 5 |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | 2 | 0 |
| Adalimumab | Injection 20 mg in 0.4 mL pre-filled syringe | 2 | 3 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | 2 | 0 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen | 2 | 2 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled pen, 6 | 1 | 0 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | 2 | 0 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe | 2 | 2 |
| Adalimumab | Injection 40 mg in 0.8 mL pre-filled syringe, 6 | 1 | 0 |
| Allopurinol | Tablet 100 mg | 200 | 2 |
| Allopurinol | Tablet 300 mg | 60 | 2 |
| Alogliptin | Tablet 12.5 mg (as benzoate) | 28 | 5 |
| Alogliptin | Tablet 25 mg (as benzoate) | 28 | 5 |
| Alogliptin | Tablet 6.25 mg (as benzoate) | 28 | 5 |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride | 56 | 5 |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride | 56 | 5 |
| Alogliptin with metformin | Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride | 56 | 5 |
| Apixaban | Tablet 2.5 mg | 60 | 0 |
| Apixaban | Tablet 5 mg | 28 | 0 |
| Aspirin | Tablet 100 mg | 112 | 1 |
| Aspirin | Tablet, dispersible, 300 mg | 96 | 0 |
| Aurothiomalate | Injection containing sodium aurothiomalate 20 mg | 10 | 1 |
| Aurothiomalate | Injection containing sodium aurothiomalate 50 mg | 10 | 1 |
| Azathioprine | Tablet 25 mg | 100 | 5 |
| Azathioprine | Tablet 50 mg | 100 | 5 |
| Benzhexol | Tablet containing benzhexol hydrochloride 2 mg | 200 | 2 |
| Benzhexol | Tablet containing benzhexol hydrochloride 5 mg | 200 | 1 |
| Betamethasone | Injection containing betamethasone acetate 3 mg with betamethasone sodium phosphate 3.9 mg in 1 mL | 5 | 0 |
| Biperiden | Tablet containing biperiden hydrochloride 2 mg | 200 | 2 |
| Bupropion | Tablet containing bupropion hydrochloride 150 mg (sustained release) | 30 | 0 |
| Bupropion | Tablet containing bupropion hydrochloride 150 mg (sustained release) | 90 | 0 |
| Calcitriol | Capsule 0.25 microgram | 100 | 3 |
| Calcium | Tablet 600 mg (as carbonate) | 240 | 1 |
| Calcium | Tablet, chewable, 500 mg (as carbonate) | 240 | 1 |
| Carbamazepine | Tablet 100 mg | 200 | 0 |
| Carbamazepine | Tablet 100 mg | 200 | 2 |
| Carbamazepine | Tablet 200 mg | 200 | 0 |
| Carbamazepine | Tablet 200 mg | 200 | 2 |
| Carbamazepine | Tablet 200 mg (controlled release) | 200 | 0 |
| Carbamazepine | Tablet 200 mg (controlled release) | 200 | 2 |
| Carbamazepine | Tablet 400 mg (controlled release) | 200 | 0 |
| Carbamazepine | Tablet 400 mg (controlled release) | 200 | 2 |
| Citalopram | Tablet 20 mg (as hydrobromide) | 28 | 5 |
| Citalopram | Tablet 40 mg (as hydrobromide) | 28 | 5 |
| Clonazepam | Tablet 2 mg | 200 | 2 |
| Clonazepam | Tablet 500 micrograms | 200 | 2 |
| Colestipol | Oral powder, sachets containing colestipol hydrochloride 5 g, 120 | 1 | 5 |
| Colestipol | Oral powder, sachets containing colestipol hydrochloride 5 g, 120 | 1 | 11 |
| Cyproheptadine | Tablet containing cyproheptadine hydrochloride 4 mg (anhydrous) | 100 | 2 |
| Dabigatran etexilate | Capsule 110 mg (as mesilate) | 60 | 0 |
| Dabigatran etexilate | Capsule 75 mg (as mesilate) | 60 | 0 |
| Dabrafenib | Capsule 50 mg (as mesilate) | 120 | 3 |
| Dabrafenib | Capsule 50 mg (as mesilate) | 120 | 5 |
| Dabrafenib | Capsule 75 mg (as mesilate) | 120 | 3 |
| Dabrafenib | Capsule 75 mg (as mesilate) | 120 | 5 |
| Dapagliflozin | Tablet 10 mg (as propanediol monohydrate) | 28 | 5 |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | 28 | 5 |
| Dapagliflozin with metformin | Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride | 28 | 5 |
| Dapagliflozin with metformin | Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride | 56 | 5 |
| Dapsone | Tablet 100 mg | 100 | 1 |
| Dapsone | Tablet 25 mg | 100 | 1 |
| Dasatinib | Tablet 100 mg | 30 | 2 |
| Dasatinib | Tablet 100 mg | 30 | 5 |
| Dasatinib | Tablet 20 mg | 60 | 2 |
| Dasatinib | Tablet 20 mg | 60 | 5 |
| Dasatinib | Tablet 50 mg | 60 | 2 |
| Dasatinib | Tablet 50 mg | 60 | 5 |
| Dasatinib | Tablet 70 mg | 60 | 2 |
| Dasatinib | Tablet 70 mg | 60 | 5 |
| Degarelix | Powder for injection 120 mg (as acetate), 2, injection set | 1 | 0 |
| Denosumab | Injection 60 mg in 1 mL pre-filled syringe | 1 | 0 |
| Desmopressin | Tablet containing desmopressin acetate 200 micrograms | 30 | 5 |
| Desmopressin | Tablet containing desmopressin acetate 200 micrograms | 90 | 5 |
| Desmopressin | Wafer 120 micrograms (as acetate) | 30 | 5 |
| Desmopressin | Wafer 240 micrograms (as acetate) | 30 | 5 |
| Desvenlafaxine | Tablet (extended release) 100 mg (as succinate) | 28 | 5 |
| Desvenlafaxine | Tablet (extended release) 50 mg (as succinate) | 28 | 5 |
| Desvenlafaxine | Tablet (modified release) 100 mg | 28 | 5 |
| Desvenlafaxine | Tablet (modified release) 100 mg (as benzoate) | 28 | 5 |
| Desvenlafaxine | Tablet (modified release) 50 mg | 28 | 5 |
| Desvenlafaxine | Tablet (modified release) 50 mg (as benzoate) | 28 | 5 |
| Digoxin | Tablet 250 micrograms | 100 | 1 |
| Digoxin | Tablet 62.5 micrograms | 200 | 1 |
| Dimethyl fumarate | Capsule (modified release) 240 mg | 56 | 5 |
| Donepezil | Tablet containing donepezil hydrochloride 10 mg | 28 | 5 |
| Donepezil | Tablet containing donepezil hydrochloride 5 mg | 28 | 5 |
| Duloxetine | Capsule 60 mg (as hydrochloride) | 28 | 5 |
| Entacapone | Tablet 200 mg | 200 | 4 |
| Erlotinib | Tablet 100 mg (as hydrochloride) | 30 | 3 |
| Erlotinib | Tablet 150 mg (as hydrochloride) | 30 | 3 |
| Erlotinib | Tablet 25 mg (as hydrochloride) | 30 | 3 |
| Escitalopram | Tablet 10 mg (as oxalate) | 28 | 5 |
| Escitalopram | Tablet 20 mg (as oxalate) | 28 | 5 |
| Esomeprazole | Capsule (enteric) 20 mg (as magnesium) | 30 | 1 |
| Esomeprazole | Capsule (enteric) 40 mg (as magnesium) | 30 | 1 |
| Esomeprazole | Tablet (enteric coated) 20 mg (as magnesium trihydrate) | 30 | 1 |
| Esomeprazole | Tablet (enteric coated) 40 mg (as magnesium trihydrate) | 30 | 1 |
| Esomeprazole and clarithromycin and amoxycillin | Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxycillin 500 mg (as trihydrate) | 1 | 0 |
| Ethosuximide | Capsule 250 mg | 200 | 2 |
| Etonogestrel | Subcutaneous implant 68 mg | 1 | 0 |
| Exenatide | Injection solution 10 micrograms per dose in pre-filled pen, 60 doses | 1 | 5 |
| Exenatide | Injection solution 5 micrograms per dose in pre-filled pen, 60 doses | 1 | 5 |
| Fingolimod | Capsule 500 micrograms (as hydrochloride) | 28 | 5 |
| Fludrocortisone | Tablet containing fludrocortisone acetate 100 micrograms | 200 | 1 |
| Fluvoxamine | Tablet containing fluvoxamine maleate 100 mg | 30 | 5 |
| Fluvoxamine | Tablet containing fluvoxamine maleate 50 mg | 30 | 5 |
| Folic acid | Tablet 5 mg | 200 | 1 |
| Folic acid | Tablet 500 micrograms | 200 | 0 |
| Frusemide | Tablet 20 mg | 100 | 1 |
| Frusemide | Tablet 40 mg | 100 | 1 |
| Gabapentin | Capsule 100 mg | 100 | 5 |
| Gabapentin | Capsule 300 mg | 100 | 5 |
| Gabapentin | Capsule 400 mg | 100 | 5 |
| Gabapentin | Tablet 600 mg | 100 | 5 |
| Gabapentin | Tablet 800 mg | 100 | 5 |
| Galantamine | Capsule (prolonged release) 16 mg (as hydrobromide) | 28 | 5 |
| Galantamine | Capsule (prolonged release) 24 mg (as hydrobromide) | 28 | 5 |
| Galantamine | Capsule (prolonged release) 8 mg (as hydrobromide) | 28 | 5 |
| Gestrinone | Capsule 2.5 mg | 8 | 5 |
| Glatiramer | Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe | 28 | 5 |
| Gliclazide | Tablet 60 mg (modified release) | 60 | 5 |
| Gliclazide | Tablet 80 mg | 100 | 5 |
| Glimepiride | Tablet 3 mg | 30 | 5 |
| Glimepiride | Tablet 4 mg | 30 | 5 |
| Goserelin | Subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe | 1 | 1 |
| Goserelin | Subcutaneous implant 3.6 mg (as acetate) in pre-filled injection syringe | 1 | 5 |
| Goserelin and bicalutamide | Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg | 1 | 0 |
| Goserelin and bicalutamide | Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 84 tablets bicalutamide 50 mg | 1 | 1 |
| Griseofulvin | Tablet 125 mg | 100 | 2 |
| Hydrochlorothiazide | Tablet 25 mg | 100 | 1 |
| Hydrochlorothiazide with amiloride | Tablet containing hydrochlorothiazide 50 mg with amiloride hydrochloride 5 mg | 100 | 1 |
| Hydrochlorothiazide with triamterene | Tablet 25 mg-50 mg | 100 | 1 |
| Hydroxocobalamin | Injection 1 mg (as acetate) in 1 mL | 3 | 0 |
| Hydroxocobalamin | Injection 1 mg (as chloride) in 1 mL | 3 | 0 |
| Hydroxychloroquine | Tablet containing hydroxychloroquine sulfate 200 mg | 100 | 1 |
| Ibandronic acid | Tablet 50 mg (as ibandronate sodium monohydrate) | 28 | 2 |
| Imatinib | Tablet 100 mg (as mesylate) | 60 | 2 |
| Imatinib | Tablet 400 mg (as mesylate) | 30 | 2 |
| Indapamide | Tablet containing indapamide hemihydrate 1.5 mg (sustained release) | 90 | 1 |
| Indapamide | Tablet containing indapamide hemihydrate 2.5 mg | 90 | 1 |
| Insulin aspart | Injection (human analogue) 100 units per mL, 10 mL vial | 5 | 2 |
| Insulin aspart | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin aspart with insulin aspart protamine suspension | Injections (human analogue), cartridges, 30 units-70 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin detemir | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin glargine | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin glulisine | Injection (human analogue) 100 units per mL, 10 mL | 5 | 2 |
| Insulin glulisine | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin isophane | Injection (bovine) 100 units per mL, 10 mL | 5 | 2 |
| Insulin isophane | Injection (human) 100 units per mL, 10 mL | 5 | 2 |
| Insulin isophane | Injections (human), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin lispro | Injection (human analogue) 100 units per mL, 10 mL vial | 5 | 2 |
| Insulin lispro | Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin lispro with insulin lispro protamine suspension | Injections (human analogue), cartridges, 25 units-75 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin lispro with insulin lispro protamine suspension | Injections (human analogue), cartridges, 50 units-50 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin neutral | Injection (bovine) 100 units per mL, 10 mL | 5 | 2 |
| Insulin neutral | Injection (human) 100 units per mL, 10 mL | 5 | 2 |
| Insulin neutral | Injections (human), cartridges, 100 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin neutral with insulin isophane | Injection (human) 30 units-70 units per mL, 10 mL | 5 | 2 |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5 | 5 | 1 |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 | 5 | 1 |
| Isotretinoin | Capsule 10 mg | 60 | 3 |
| Isotretinoin | Capsule 20 mg | 60 | 3 |
| Isotretinoin | Capsule 40 mg | 30 | 3 |
| Ketoprofen | Capsule 200 mg (sustained release) | 28 | 0 |
| Ketoprofen | Capsule 200 mg (sustained release) | 28 | 3 |
| Lacosamide | Tablet 100 mg | 56 | 5 |
| Lacosamide | Tablet 150 mg | 56 | 5 |
| Lacosamide | Tablet 200 mg | 56 | 5 |
| Lamotrigine | Tablet 100 mg | 56 | 5 |
| Lamotrigine | Tablet 200 mg | 56 | 5 |
| Lamotrigine | Tablet 25 mg | 56 | 5 |
| Lamotrigine | Tablet 5 mg | 56 | 5 |
| Lamotrigine | Tablet 50 mg | 56 | 5 |
| Lansoprazole | Capsule 30 mg | 28 | 1 |
| Lansoprazole | Tablet 30 mg (orally disintegrating) | 28 | 1 |
| Leuprorelin | I.M. injection (3 month modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe | 1 | 1 |
| Leuprorelin | I.M. injection (modified release), powder for injection containing leuprorelin acetate 22.5 mg with diluent in pre-filled dual-chamber syringe | 1 | 1 |
| Leuprorelin | I.M. injection (modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe | 1 | 1 |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set | 1 | 1 |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set | 1 | 1 |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set | 1 | 0 |
| Leuprorelin | Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set | 1 | 5 |
| Levetiracetam | Oral solution 100 mg per mL, 300 mL | 1 | 5 |
| Levetiracetam | Tablet 1 g | 60 | 5 |
| Levetiracetam | Tablet 250 mg | 60 | 5 |
| Levetiracetam | Tablet 500 mg | 60 | 5 |
| Levodopa with carbidopa and entacapone | Tablet 100 mg-25 mg-200 mg | 200 | 4 |
| Levodopa with carbidopa and entacapone | Tablet 125 mg-31.25 mg-200 mg | 200 | 4 |
| Levodopa with carbidopa and entacapone | Tablet 150 mg-37.5 mg-200 mg | 200 | 4 |
| Levodopa with carbidopa and entacapone | Tablet 200 mg-50 mg-200 mg | 200 | 4 |
| Levodopa with carbidopa and entacapone | Tablet 50 mg-12.5 mg-200 mg | 200 | 4 |
| Levodopa with carbidopa and entacapone | Tablet 75 mg-18.75 mg-200 mg | 200 | 4 |
| Levonorgestrel | Intrauterine drug delivery system 52 mg | 1 | 0 |
| Levonorgestrel | Tablets 30 micrograms, 28 | 4 | 2 |
| Levonorgestrel with ethinyloestradiol | Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets | 4 | 2 |
| Levonorgestrel with ethinyloestradiol | Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets | 4 | 2 |
| Levonorgestrel with ethinyloestradiol | Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets | 4 | 2 |
| Levonorgestrel with ethinyloestradiol | Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets | 4 | 2 |
| Linagliptin | Tablet 5 mg | 30 | 5 |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride | 60 | 5 |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride | 60 | 5 |
| Linagliptin with metformin | Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride | 60 | 5 |
| Liothyronine | Tablet containing liothyronine sodium 20 micrograms | 100 | 2 |
| Lisdexamfetamine | Capsule containing lisdexamfetamine dimesilate 50 mg | 30 | 5 |
| Medroxyprogesterone | Injection containing medroxyprogesterone acetate 150 mg in 1 mL | 1 | 1 |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 10 mg | 30 | 2 |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 10 mg | 100 | 2 |
| Medroxyprogesterone | Tablet containing medroxyprogesterone acetate 5 mg | 56 | 2 |
| Megestrol | Tablet containing megestrol acetate 160 mg | 30 | 2 |
| Meloxicam | Capsule 15 mg | 30 | 3 |
| Meloxicam | Tablet 15 mg | 30 | 3 |
| Memantine | Tablet containing memantine hydrochloride 10 mg | 56 | 5 |
| Memantine | Tablet containing memantine hydrochloride 20 mg | 28 | 5 |
| Metformin | Tablet (extended release) containing metformin hydrochloride 1 g | 60 | 5 |
| Metformin | Tablet (extended release) containing metformin hydrochloride 500 mg | 120 | 5 |
| Metformin | Tablet containing metformin hydrochloride 1 g | 90 | 5 |
| Metformin | Tablet containing metformin hydrochloride 500 mg | 100 | 5 |
| Metformin | Tablet containing metformin hydrochloride 850 mg | 60 | 5 |
| Metformin with glibenclamide | Tablet containing metformin hydrochloride 250 mg with glibenclamide 1.25 mg | 90 | 5 |
| Metformin with glibenclamide | Tablet containing metformin hydrochloride 500 mg with glibenclamide 2.5 mg | 90 | 5 |
| Metformin with glibenclamide | Tablet containing metformin hydrochloride 500 mg with glibenclamide 5 mg | 90 | 5 |
| Methylprednisolone | Injection containing methylprednisolone acetate 40 mg in 1 mL | 5 | 0 |
| Mirtazapine | Tablet 45 mg | 30 | 5 |
| Mirtazapine | Tablet 45 mg (orally disintegrating) | 30 | 5 |
| Moclobemide | Tablet 150 mg | 60 | 5 |
| Moclobemide | Tablet 300 mg | 60 | 5 |
| Montelukast | Tablet, chewable, 4 mg (as sodium) | 28 | 5 |
| Montelukast | Tablet, chewable, 5 mg (as sodium) | 28 | 5 |
| Nafarelin | Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses | 1 | 5 |
| Naproxen | Tablet 1 g (sustained release) | 28 | 0 |
| Naproxen | Tablet 1 g (sustained release) | 28 | 3 |
| Naproxen | Tablet 750 mg (sustained release) | 28 | 0 |
| Naproxen | Tablet 750 mg (sustained release) | 28 | 3 |
| Norethisterone | Tablets 350 micrograms, 28 | 4 | 2 |
| Norethisterone with ethinyloestradiol | Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets | 4 | 2 |
| Norethisterone with ethinyloestradiol | Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets | 4 | 2 |
| Norethisterone with mestranol | Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets | 4 | 2 |
| Oestradiol | Tablet 2 mg | 56 | 2 |
| Oestradiol | Tablet containing oestradiol valerate 1 mg | 56 | 2 |
| Oestradiol | Tablet containing oestradiol valerate 2 mg | 56 | 2 |
| Omeprazole | Capsule 20 mg | 30 | 1 |
| Omeprazole | Tablet 20 mg | 30 | 1 |
| Omeprazole | Tablet 20 mg (as magnesium) | 30 | 1 |
| Oxcarbazepine | Tablet 600 mg | 100 | 5 |
| Oxybutynin | Tablet containing oxybutynin hydrochloride 5 mg | 100 | 5 |
| Oxybutynin | Transdermal patches 36 mg, 8 | 1 | 5 |
| Pantoprazole | Sachet containing granules 40 mg (as sodium sesquihydrate) | 30 | 2 |
| Pantoprazole | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | 30 | 2 |
| Paracetamol | Tablet 500 mg | 300 | 0 |
| Paracetamol | Tablet 665 mg (modified release) | 192 | 5 |
| Paroxetine | Tablet 20 mg (as hydrochloride) | 30 | 5 |
| Paroxetine | Tablet 20 mg (as mesilate) | 30 | 5 |
| Pazopanib | Tablet 200 mg (as hydrochloride) | 90 | 2 |
| Pazopanib | Tablet 400 mg (as hydrochloride) | 60 | 2 |
| Perampanel | Tablet 10 mg (as hemisesquihydrate) | 28 | 5 |
| Perampanel | Tablet 12 mg (as hemisesquihydrate) | 28 | 5 |
| Perampanel | Tablet 4 mg (as hemisesquihydrate) | 28 | 5 |
| Perampanel | Tablet 6 mg (as hemisesquihydrate) | 28 | 5 |
| Perampanel | Tablet 8 mg (as hemisesquihydrate) | 28 | 5 |
| Phenobarbitone | Tablet 30 mg | 200 | 4 |
| Phenytoin | Capsule containing phenytoin sodium 100 mg | 200 | 2 |
| Phenytoin | Capsule containing phenytoin sodium 30 mg | 200 | 2 |
| Phenytoin | Tablet 50 mg | 200 | 2 |
| Pioglitazone | Tablet 45 mg (as hydrochloride) | 28 | 5 |
| Pizotifen | Tablet 500 micrograms (as malate) | 100 | 2 |
| Potassium chloride | Tablet 600 mg (sustained release) | 200 | 1 |
| Potassium chloride with potassium bicarbonate | Tablet, effervescent, 14 mmol potassium and 8 mmol chloride | 60 | 1 |
| Pregabalin | Capsule 300 mg | 56 | 5 |
| Primidone | Tablet 250 mg | 200 | 2 |
| Propantheline | Tablet containing propantheline bromide 15 mg | 200 | 5 |
| Quinagolide | Tablet 75 micrograms (as hydrochloride) | 30 | 5 |
| Rabeprazole | Tablet containing rabeprazole sodium 20 mg (enteric coated) | 30 | 2 |
| Reboxetine | Tablet 4 mg (as mesilate) | 60 | 5 |
| Rifaximin | Tablet 550 mg | 56 | 5 |
| Risedronic acid | Tablet containing risedronate sodium 30 mg | 28 | 1 |
| Rivastigmine | Capsule 1.5 mg (as hydrogen tartrate) | 56 | 5 |
| Rivastigmine | Capsule 3 mg (as hydrogen tartrate) | 56 | 5 |
| Rivastigmine | Capsule 4.5 mg (as hydrogen tartrate) | 56 | 5 |
| Rivastigmine | Capsule 6 mg (as hydrogen tartrate) | 56 | 5 |
| Rivastigmine | Transdermal patch 18 mg | 30 | 5 |
| Rivastigmine | Transdermal patch 27 mg | 30 | 5 |
| Rivastigmine | Transdermal patch 9 mg | 30 | 5 |
| Rosiglitazone | Tablet 8 mg (as maleate) | 28 | 5 |
| Rosiglitazone with metformin | Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride | 56 | 5 |
| Rosiglitazone with metformin | Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride | 56 | 5 |
| Rosiglitazone with metformin | Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride | 56 | 5 |
| Rosiglitazone with metformin | Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride | 56 | 5 |
| Rotigotine | Transdermal patch 13.5 mg | 28 | 5 |
| Rotigotine | Transdermal patch 4.5 mg | 28 | 5 |
| Rotigotine | Transdermal patch 9 mg | 28 | 5 |
| Sapropterin | Tablet (soluble) containing sapropterin dihydrochloride 100 mg | 180 | 0 |
| Saxagliptin | Tablet 2.5 mg (as hydrochloride) | 28 | 5 |
| Saxagliptin | Tablet 5 mg (as hydrochloride) | 28 | 5 |
| Saxagliptin with metformin | Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | 56 | 5 |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride | 28 | 5 |
| Saxagliptin with metformin | Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride | 28 | 5 |
| Sertraline | Tablet 100 mg (as hydrochloride) | 30 | 5 |
| Sertraline | Tablet 50 mg (as hydrochloride) | 30 | 5 |
| Sitagliptin | Tablet 100 mg (as phosphate monohydrate) | 28 | 5 |
| Sitagliptin | Tablet 25 mg (as phosphate monohydrate) | 28 | 5 |
| Sitagliptin | Tablet 50 mg (as phosphate monohydrate) | 28 | 5 |
| Sitagliptin with metformin | Tablet (modified release) containing 100 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride | 28 | 5 |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride | 56 | 5 |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride | 56 | 5 |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride | 56 | 5 |
| Sitagliptin with metformin | Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride | 56 | 5 |
| Sorafenib | Tablet 200 mg (as tosylate) | 120 | 2 |
| Sorafenib | Tablet 200 mg (as tosylate) | 120 | 5 |
| Sucralfate | Tablet equivalent to 1 g anhydrous sucralfate | 120 | 2 |
| Sulthiame | Tablet 200 mg | 200 | 2 |
| Sulthiame | Tablet 50 mg | 200 | 2 |
| Sunitinib | Capsule 12.5 mg (as malate) | 28 | 1 |
| Sunitinib | Capsule 12.5 mg (as malate) | 28 | 2 |
| Sunitinib | Capsule 12.5 mg (as malate) | 28 | 3 |
| Sunitinib | Capsule 12.5 mg (as malate) | 28 | 5 |
| Sunitinib | Capsule 25 mg (as malate) | 28 | 1 |
| Sunitinib | Capsule 25 mg (as malate) | 28 | 2 |
| Sunitinib | Capsule 25 mg (as malate) | 28 | 3 |
| Sunitinib | Capsule 25 mg (as malate) | 28 | 5 |
| Sunitinib | Capsule 37.5 mg (as malate) | 28 | 1 |
| Sunitinib | Capsule 37.5 mg (as malate) | 28 | 2 |
| Sunitinib | Capsule 37.5 mg (as malate) | 28 | 3 |
| Sunitinib | Capsule 37.5 mg (as malate) | 28 | 5 |
| Sunitinib | Capsule 50 mg (as malate) | 28 | 1 |
| Sunitinib | Capsule 50 mg (as malate) | 28 | 2 |
| Sunitinib | Capsule 50 mg (as malate) | 28 | 3 |
| Sunitinib | Capsule 50 mg (as malate) | 28 | 5 |
| Tacrolimus | Capsule 0.5 mg (once daily prolonged release) | 30 | 3 |
| Tacrolimus | Capsule 1 mg (once daily prolonged release) | 60 | 3 |
| Tacrolimus | Capsule 5 mg (once daily prolonged release) | 30 | 3 |
| Tamoxifen | Tablet 20 mg (as citrate) | 60 | 5 |
| Temozolomide | Capsule 100 mg | 15 | 2 |
| Temozolomide | Capsule 140 mg | 15 | 2 |
| Temozolomide | Capsule 20 mg | 15 | 2 |
| Temozolomide | Capsule 5 mg | 15 | 2 |
| Terbinafine | Tablet 250 mg (as hydrochloride) | 42 | 0 |
| Terbinafine | Tablet 250 mg (as hydrochloride) | 42 | 1 |
| Teriflunomide | Tablet 14 mg | 28 | 5 |
| Testosterone | I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL | 1 | 1 |
| Testosterone | Injection containing testosterone enanthate 250 mg in 1 mL | 3 | 3 |
| Testosterone | Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2 | 1 | 4 |
| Tetrabenazine | Tablet 25 mg | 112 | 5 |
| Thyroxine | Tablet containing 100 micrograms anhydrous thyroxine sodium | 200 | 1 |
| Thyroxine | Tablet containing 200 micrograms anhydrous thyroxine sodium | 200 | 1 |
| Thyroxine | Tablet containing 50 micrograms anhydrous thyroxine sodium | 200 | 1 |
| Thyroxine | Tablet containing 75 micrograms anhydrous thyroxine sodium | 200 | 1 |
| Tiagabine | Tablet 10 mg (as hydrochloride) | 100 | 5 |
| Tiagabine | Tablet 15 mg (as hydrochloride) | 100 | 5 |
| Tiagabine | Tablet 5 mg (as hydrochloride) | 100 | 5 |
| Tiludronic acid | Tablet 200 mg (as tiludronate disodium) | 56 | 2 |
| Tiotropium | Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations) | 1 | 5 |
| Topiramate | Capsule 15 mg | 60 | 5 |
| Topiramate | Capsule 25 mg | 60 | 5 |
| Topiramate | Capsule 50 mg | 60 | 5 |
| Topiramate | Tablet 100 mg | 60 | 5 |
| Topiramate | Tablet 200 mg | 60 | 5 |
| Topiramate | Tablet 25 mg | 60 | 5 |
| Topiramate | Tablet 50 mg | 60 | 5 |
| Triamcinolone | Injection containing triamcinolone acetonide 10 mg in 1 mL | 5 | 0 |
| Triptorelin | Powder for I.M. injection (prolonged release) 11.25 mg (as embonate) with solvent, syringe and needles | 1 | 1 |
| Triptorelin | Powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles | 1 | 0 |
| Ustekinumab | Injection 45 mg in 0.5 mL | 1 | 1 |
| Valproic acid | Tablet (enteric coated) containing sodium valproate 200 mg | 200 | 2 |
| Valproic acid | Tablet (enteric coated) containing sodium valproate 500 mg | 200 | 2 |
| Varenicline | 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 | 1 | 0 |
| Varenicline | Tablet 1 mg (as tartrate) | 56 | 2 |
| Varenicline | Tablet 1 mg (as tartrate) | 112 | 0 |
| Venlafaxine | Capsule (modified release) 150 mg (as hydrochloride) | 28 | 5 |
| Venlafaxine | Capsule (modified release) 75 mg (as hydrochloride) | 28 | 5 |
| Vigabatrin | Oral powder, sachet 500 mg | 60 | 5 |
| Vigabatrin | Tablet 500 mg | 100 | 5 |
| Vildagliptin | Tablet 50 mg | 60 | 5 |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride | 60 | 5 |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride | 60 | 5 |
| Vildagliptin with metformin | Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride | 60 | 5 |
| Zonisamide | Capsule 100 mg | 112 | 5 |
| Zonisamide | Capsule 25 mg | 56 | 5 |
| Zonisamide | Capsule 50 mg | 56 | 5 |

# Table 6. Deletions

|  |  |  |  |
| --- | --- | --- | --- |
| **Listed drug** | **Form** | **Maximum quantity** | **Maximum number of repeats** |
| Aripiprazole | Powder for injection 300 mg (as monohydrate) with diluent | 1 | 5 |
| Aripiprazole | Powder for injection 400 mg (as monohydrate) with diluent | 1 | 5 |
| Denosumab | Injection 120 mg in 1.7 mL | 1 | 5 |
| Ponatinib | Tablet 15 mg (as hydrochloride) | 60 | 5 |
| Ponatinib | Tablet 45 mg (as hydrochloride) | 30 | 5 |
| Tofacitinib | Tablet 5 mg | 56 | 5 |

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***National Health (Pharmaceutical benefits – early supply) Instrument 2015* (PB 120 of 2015)**

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011.*

**Overview of the Legislative Instrument**

This Instrument specifies the pharmaceutical items that are in pharmaceutical benefits for which Pharmaceutical Benefits Scheme (PBS) safety net entitlements will not apply for early supplies, and to specify the period following a previous supply that constitutes an early supply.

An early supply occurs if a specified pharmaceutical benefit is resupplied within the specified period after a previous supply of the same or an equivalent pharmaceutical benefit.

The effect of being an early supply is that the patient payment for the early supply prescription does not count towards the PBS safety net threshold, and, if the PBS safety net threshold has been reached and PBS safety net would normally allow a concessional or nil contribution, the patient payment and the amount paid by the Commonwealth to the pharmacy or other approved supplier revert to pre-PBS safety net amounts.

The Instrument implements a measure to expand application of PBS safety net early supply rules contained in the PBS Access and Sustainability Package (the Package) announced by the Australian Government in May 2015.

**Human rights implications**

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS assists with advancement of this human right byproviding subsidised access to medicines for Australians. The role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The extension of safety net early supply rules to apply to a wider range of medicines will mean that safety net benefits will not apply for resupplies of more medicines, if they are obtained as early supplies. However, this is justified as early supply arrangements support the quality use of medicines and responsible use of PBS entitlements as well as discouraging waste and reducing the quantity of unused medicines in the community. The extension of early supply will also result in savings to the PBS. The listing of new and innovative medicines relies on using PBS funding responsibly and keeping the PBS sustainable.

The measures in the Package, including early supply changes, are the result of consultation and negotiation with stakeholders across the PBS supply chain, including the pharmaceutical industry, pharmacy groups and consumers. Together, the measures provide a fair and balanced approach in which benefits and savings are shared across PBS stakeholders to ensure continued and improved access to medicines for consumers.

**Conclusion**

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

**The Hon Sussan Ley MP, Minister for Health**