Pharmaceutical Management Agency

Section H Update for Hospital Pharmaceuticals

Effective 1 October 2018

Cumulative for August, September and October 2018



Contents

Summary of decisions effective 1 October 2018	3
Section H changes to Part II	6
Index	32

Summary of decisions EFFECTIVE 1 OCTOBER 2018

- Alprostadil (Prostin VR) inj 500 mcg per ml, 1 ml ampoule price increase and addition of HSS
- Amino acid formula (without phenylalanine) (e.g. XP Maxamaid) powder
 25 g protein and 51 g carbohydrate per 100 g, 500 g can to be delisted
 1 April 2019
- Aqueous cream (Boucher) crm 500 g new listing and addition of HSS
- Aqueous cream (AFT SLS-free) crm 500 g to be delisted 1 December 2018
- Azacitidine (Azacitidine Dr Reddy's) inj 100 mg vial new listing and addition of HSS
- Azacitidine (Vidaza) inj 100 mg vial to be delisted 1 December 2018
- Azithromycin (Zithromax) grans for oral liq 200 mg per 5 ml (40 mg per ml),
 15 ml price increase and addition of HSS
- Basiliximab (Simulect) inj 20 mg vial price decrease
- Benzathine benzylpenicillin (Bicillin LA) inj 900 mg (1.2 million units) in 2.3 ml syringe – price increase and addition of HSS
- Betamethasone valerate (Betnovate) lotn 0.1%, 50 ml new listing and addition of HSS
- Betamethasone dipropionate with calcipotriol (Daivobet) gel 500 mcg with calcipotriol 50 mcg per g, 60 g new listing and addition of HSS
- Betamethasone dipropionate with calcipotriol (Daivobet) gel 500 mcg with calcipotriol 50 mcg per g, 30 g to be delisted 1 December 2018
- Betamethasone dipropionate with calcipotriol (Daivobet) oint 500 mcg with calcipotriol 50 mcg per g, 30 g price decrease and addition of HSS
- Bezafibrate tab 200 mg (Bezalip) and tab long-acting 400 mg (Bezalip Retard)
 price increase and addition of HSS
- Bleomycin sulphate (DBL Bleomycin Sulfate) inj 15,000 iu vial price increase and addition of HSS
- Cyproterone acetate (Siterone) tab 50 mg and 100 mg new listing and addition of HSS
- Cyproterone acetate (Procur) tab 50 mg and 100 mg to be delisted
 December 2018
- Cytarabine (Pfizer) inj 100 mg per ml, 20 ml vial addition of HSS
- Eltrombopag (Revolade) tab 25 mg and 50 mg price decrease and amended restriction
- Eplerenone (Inspra) tab 50 mg new listing and addition of HSS

Summary of decisions – effective 1 October 2018 (continued)

- Ethambutol hydrochloride (Myambutol) tab 100 mg to be delisted
 1 February 2019
- Felodipine tab long-acting 5 mg (Felo 5 ER) and tab long-acting 10 mg (Felo 10 ER) – new listing and addition of HSS
- Felodipine (Plendil ER) tab long-acting 5 mg and 10 mg to be delisted
 1 December 2018
- Fingolimod (Gilenya) cap 0.5 mg price decrease
- Flumazenil (Hameln) inj 0.1 mg per ml, 5 ml ampoule new listing and addition of HSS
- Flumazenil (Anexate) inj 0.1 mg per ml, 5 ml ampoule to be delisted
 December 2018
- Glipizide (Minidiab) tab 5 mg price increase and addition of HSS
- Granisetron (Deva) inj 1 mg per ml, 3 ml ampoule new listing and addition of HSS
- Heparin sodium inj 1,000 iu per ml, 35 ml vial to be delisted 1 May 2019
- Iron polymaltose (Ferrum H) inj 50 mg per ml, 2 ml ampoule to be delisted
 1 April 2019
- Lidocaine [lignocaine] hydrochloride (Lidocaine-Claris) inj 1%, 20 ml ampoule and inj 2%, 20 ml ampoule to be delisted 1 February 2019
- Linezolid (Zyvox) oral liq 20 mg per ml price increase and addition of HSS
- Lisinopril (Ethics Lisinopril) tab 5 mg, 10 mg and 20 mg price increase and addition of HSS
- Lithium carbonate (Lithicarb FC) tab 400 mg to be delisted 1 March 2019
- Metformin hydrochloride (Apotex) tab immediate-release 500 mg new listing and addition of HSS
- Metformin hydrochloride (Metchek) tab immediate-release 500 mg to be delisted 1 February 2019
- Methylprednisolone (as sodium succinate) tab 4 mg and 100 mg (Medrol), and inj 1 g vial (Solu-Medrol) – price increase and addition of HSS
- Methylprednisolone (as sodium succinate) (Solu-Medrol Act-O-Vial) inj 40 mg, 125 mg and 500 mg vial – brand name change, price increase and addition of HSS
- Methylprednisolone acetate (Depo-Medrol) inj 40 mg per ml, 1 ml vial
 price increase and addition of HSS
- Morphine hydrochloride (RA-Morph) oral liq 1 mg per ml, 2 mg per ml, 5 mg per ml and 10 mg per ml – price increase and addition of HSS

Summary of decisions – effective 1 October 2018 (continued)

- Naproxen tab 250 mg (Noflam 250) and tab 500 mg (Noflam 500)
 price increase and addition of HSS
- Nintedanib (Ofev) cap 100 mg and 150 mg new listing
- Oil in water emulsion (healthE Fatty Cream) crm, 100 g price decrease and addition of HSS
- Omalizumab (Xolair) inj 150 mg prefilled syringe new listing
- Omalizumab (Xolair) inj 150 mg vial price decrease and amended restriction
- Pirfenidone (Esbriet) cap 267 mg amended restriction
- Quinapril with hydrochlorothiazide tab 10 mg with hydrochlorothiazide
 12.5 mg (Accuretic 10) and tab 20 mg with hydrochlorothiazide 12.5 mg
 (Accuretic 20) price increase and addition of HSS
- Ruxolitinib (Jakavi) tab 5 mg, 15 mg and 20 mg new listing
- Sacubitril with valsartan tab 24.3 mg with valsartan 25.7 mg (Entresto 24/26), tab 48.6 mg with valsartan 51.4 mg (Entresto 49/51) and tab 97.2 mg with valsartan 102.8 mg (Entresto 97/103) new listing
- Secukinumab (Cosentyx) inj 150 mg per ml, 1 ml prefilled syringe new listing
- Solifenacin succinate (Solifenacin Mylan) tab 5 mg and 10 mg new listing and addition of HSS
- Solifenacin succinate (Vesicare) tab 5 mg and 10 mg restriction applies to this brand only and to be delisted 1 December 2018
- Tacrolimus (Tacrolimus Sandoz) cap 0.5 mg, 1 mg and 5 mg HSS removed, price decrease and amended restriction
- Tacrolimus inj 5 mg per ml, 1 ml ampoule –amended restriction
- Tiotropium bromide soln for inhalation 2.5 mcg per dose (Spiriva Respimat) and powder for inhalation 18 mcg per dose (Spiriva) – restriction removed
- Ursodeoxycholic acid (Ursosan) cap 250 mg amended restriction
- Vildagliptin (Galvus) tab 50 mg new listing
- Vildagliptin with metformin hydrochloride (Galvumet) tab 50 mg with 850 mg metformin hydrochloride and tab 50 mg with 1,000 mg metformin hydrochloride new listing
- Vitamin A with vitamins D and C (e.g. Vitadol C) soln 1,000 u with vitamin D
 400 u and ascorbic acid 30 mg per 10 drops to be delisted 1 August 2019
- Voriconazole (Vfend) powder for oral suspension 40 mg per ml, 70 ml
 price increase and addition of HSS
- Zopiclone (Zopiclone Actavis) tab 7.5 mg, 500 tab pack delisted 1 October 2018

Price (ex man. Excl. GST) \$ Pe Brand or Generic Manufacturer

Section H changes to Part II

Effective 1 October 2018

ALIMENTARY TRACT AND METABOLISM

10	GLIPIZIDE († price and addition of HSS) Tab 5 mg – 1% DV Dec-18 to 2021	100	Minidiab
10	METFORMIN HYDROCHLORIDE (brand change) Tab immediate-release 500 mg – 1% DV Feb-19 to 2021 8.63 Note – Metchek tab immediate-release 500 mg to be delisted from 1 February	1,000 2019.	Apotex
10	VILDAGLIPTIN (new listing) Tab 50 mg40.00	60	Galvus
10	VILDAGLIPTIN WITH METFORMIN HYDROCHLORIDE (new listing) Tab 50 mg with 850 mg metformin hydrochloride	60 60	Galvumet Galvumet
10	URSODEOXYCHOLIC ACID (amended restriction – affected criteria shown only → Cap 250 mg – 1% DV Sep-17 to 202037.95 Restricted Initiation — Girrhosis Primary biliary cholangitis Both: 1 Primary biliary eirrhosis cholangitis confirmed by antimitochondrial antibod cholestatic liver enzymes with or without raised serum IgM or, if AMA is nee 2 Patient not requiring a liver transplant (bilirubin > 100 pumol/l; decompens	100 ly titre (AM gative, by li	ver biopsy; and
17	IRON POLYMALTOSE (delisting) Inj 50 mg per ml, 2 ml ampoule	5 119.	Ferrum H
19	VITAMIN A WITH VITAMINS D AND C (delisting) Soln 1,000 u with vitamin D 400 u and ascorbic acid 30 mg per 10 drops Note – Vitamin A with vitamins D and C soln to be delisted from 1 August 2019	9.	e.g. Vitadol C

Price Brand or (ex man. Excl. GST) Generic \$ Per Manufacturer

Changes to Section H Part II – effective 1 October 2018 (continued)

BLOOD AND BLOOD FORMING ORGANS

24 ELTROMBOPAG (‡ price and amended restriction – affected criteria shown only)

→	· Tab 25 mg	1,550.00	28	Revolade
→	Tab 50 mg	3,100.00	28	Revolade

Restricted

Initiation - idiopathic thrombocytopenic purpura contraindicated to splenectomy

Haematologist

Reassessment required after 3 months

All of the following:

- 1 Patient has a significant and well-documented contraindication to splenectomy for clinical reasons; and
- 2 Two immunosuppressive therapies have been trialled and failed after therapy of 3 months each (or 1 month for rituximab); and
- 3 Either:
 - 3.1 Patient has immune thrombocytopenic purpura* with a platelet count of less than or equal to 20,000 platelets per microliter; or
 - 3.2 Patient has immune thrombocytopenic purpura* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

Continuation - idiopathic thrombocytopenic purpura contraindicated to splenectomy

Haematologist

Reassessment required after 12 months

All of the following:

- 1 The patient's significant contraindication to splenectomy remains; and
- 2 The patient has obtained a response from treatment during the initial approval period; and
- 3 Patient has maintained a platelet count of at least 50,000 platelets per microlitre on treatment; and
- 4 Further treatment with eltrombopag is required to maintain response.

Initiation - severe aplastic anaemia

Haematologist

Reassessment required after 3 months

Roth:

- 1 Two immunosuppressive therapies have been trialled and failed after therapy of at least 3 months duration; and
- 2 Either:
 - 2.1 Patient has severe aplastic anaemia with a platelet count of less than or equal to 20,000 platelets per microliter; or
 - 2.2 Patient has severe aplastic anaemia with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding.

Continuation - severe aplastic anaemia

Haematologist

Reassessment required after 12 months

Both:

- 1 The patient has obtained a response from treatment of at least 20,000 platelets per microlitre above baseline during the initial approval period; and
- 2 Platelet transfusion independence for a minimum of 8 weeks during the initial approval period.

28 HEPARIN SODIUM (delisting)

Inj 1,000 iu per ml, 35 ml vial

Note – Heparin sodium inj 1,000 iu per ml, 35 ml vial to be delisted from 1 May 2019.

	Price (ex man. Excl. GST)		Brand or
			Generic
	\$	Per	Manufacturer

Changes to Section H Part II - effective 1 October 2018 (continued)

CARDIOVASCULAR SYSTEM

35	LISINOPRIL († price and addition of HSS)			
	Tab 5 mg - 1% DV Dec-18 to 2021	2.07	90	Ethics Lisinopril
	Tab 10 mg – 1% DV Dec-18 to 2021	2.36	90	Ethics Lisinopril
	Tab 20 mg – 1% DV Dec-18 to 2021		90	Ethics Lisinopril
35	QUINAPRIL WITH HYDROCHLOROTHIAZIDE († price and a Tab 10 mg with hydrochlorothiazide 12.5 mg	addition of HSS)		
	– 1% DV Dec-18 to 2021	3.83	30	Accuretic 10
	Tab 20 mg with hydrochlorothiazide 12.5 mg			
	– 1% DV Dec-18 to 2021	4.92	30	Accuretic 20
36	SACUBITRIL WITH VALSARTAN (new listing)			
	→ Tab 24.3 mg with valsartan 25.7 mg	190.00	56	Entresto 24/26
	→ Tab 48.6 mg with valsartan 51.4 mg	190.00	56	Entresto 49/51
	→ Tab 97.2 mg with valsartan 102.8 mg	190.00	56	Entresto 97/103
	Doctrictod			

Restricted

Initiation

Reassessment required after 12 months

All of the following:

- 1 Patient has heart failure; and
- 2 Any of the following:
 - 2.1 Patient is in NYHA/WHO functional class II: or
 - 2.2 Patient is in NYHA/WHO functional class III; or
 - 2.3 Patient is in NYHA/WHO functional class IV: and
- 3 Patient has a documented left ventricular ejection fraction (LVEF) of less than or equal to 35%; and
- 4 Patient is receiving concomitant optimal standard chronic heart failure treatments.

Continuation

Reassessment required after 12 months

The treatment remains appropriate and the patient is benefiting from treatment.

Note: Due to the angiotensin II receptor blocking activity of sacubitril with valsartan it should not be coadministered with an ACE inhibitor or another ARB.

LLOD.	i iit (braila change)			
Tab I	ong-acting 5 mg – 1% DV Dec-18 to 2021	. 3.93	90	Felo 5 ER
Tab I	ong-acting 10 mg - 1% DV Dec-18 to 2021	.4.32	90	Felo 10 ER
ملما	Diandii ED tab lang action E was and 10 was to be delicted for	1 [0.100 as descent	

Note – Plendil ER tab long-acting 5 mg and 10 mg to be delisted from 1 December 2018.

41 BEZAFIBRATE († price and addition of HSS)

1ad 200 mg – 1% DV Dec-18 to 202 1	19.01	90	Bezalip
Tab long-acting 400 mg – 1% DV Dec-18 to 2021	12.89	30	Bezalip Retard

41 EPLERENONE (new listing and addition of HSS)

→ Tab	50 mg –	1% עע	Dec-18 to	2021		17.00	30	Inspra
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44 ALPROSTADIL HYDROCHLORIDE († price and addition of HSS)

Inj 500 mcg per ml, 1 ml ampoule

– 1% DV Dec-18 to 2021	1,765.50	5	Prostin VR
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Price		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

Changes to Section H Part II – effective 1 October 2018 (continued)

DERMATOLOGICALS

51	AQUEOUS CREAM (brand change) Crm 500 g – 1% DV Dec-18 to 2021	500 g	Boucher
51	OIL IN WATER EMULSION (\$\pi\$ price and addition of HSS) Crm, 100 g - 1% DV Dec-18 to 20211.44	100 g	healthE Fatty Cream
52	BETAMETHASONE VALERATE (new listing) Lotn 0.1% – 1% DV Dec-18 to 2021	50 ml	Betnovate
53	BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL (pack size change Gel 500 mcg with calcipotriol 50 mcg per g – 1% DV Dec-18 to 2021	and addition 60 g	of HSS) Daivobet
53	BETAMETHASONE DIPROPIONATE WITH CALCIPOTRIOL (\$\psi\$ price and addition of \$100 mcg with calcipotriol \$100 mcg per g \$100 mcg per \$100	on of HSS) 30 g	Daivobet
GENIT	O-URINARY SYSTEM		
58	SOLIFENACIN SUCCINATE (new listing) Tab 5 mg – 1% DV Dec-18 to 2021 3.00 Tab 10 mg – 1% DV Dec-18 to 2021 5.50	30 30	Solifenacin Mylan Solifenacin Mylan
58	SOLIFENACIN SUCCINATE (restriction only applies to brand below) → Tab 5 mg	30 30	Vesicare Vesicare
HORM	IONE PREPARATIONS		
60	CYPROTERONE ACETATE (brand change) Tab 50 mg – 1% DV Dec-18 to 2021	50 50	Siterone Siterone
62	METHYLPREDNISOLONE (AS SODIUM SUCCINATE) († price and addition of Tab 4 mg – 1% DV Dec-18 to 2021	HSS) 100 20 1	Medrol Medrol Solu-Medrol

Price		Brand or
(ex man. Excl. GS	ST)	Generic
\$	Per	Manufacturer

Chan	ges to Section H Part II – effective 1 October 2018 (contin	ued)	
62	METHYLPREDNISOLONE (AS SODIUM SUCCINATE) (brand name change Inj 40 mg vial – 1% DV Dec-18 to 202118.90	, † price and a	ddition of HSS) Solu-Medrol Act-O-Vial
	Inj 125 mg vial – 1% DV Dec-18 to 2021 28.90	1	Solu-Medrol Act-O-Vial
	Inj 500 mg vial – 1% DV Dec-18 to 2021 22.78	1	Solu-Medrol Act-O-Vial
62	METHYLPREDNISOLONE ACETATE († price and addition of HSS) Inj 40 mg per ml, 1 ml vial – 1% DV Dec-18 to 2021	5	Depo-Medrol
INFEC	ETIONS		
72	AZITHROMYCIN († price and addition of HSS) → Grans for oral liq 200 mg per 5 ml (40 mg per ml) - 1% DV Dec-18 to 2021	15 ml	Zithromax
74	BENZATHINE BENZYLPENICILLIN († price and addition of HSS) Inj 900 mg (1.2 million units) in 2.3 ml syringe - 1% DV Dec-18 to 2021	10	Bicillin LA
77	LINEZOLID († price and addition of HSS) → Oral liq 20 mg per ml – 1% DV Dec-18 to 20211,879.00	150 ml	Zyvox
79	VORICONAZOLE (↑ price and addition of HSS) → Powder for oral suspension 40 mg per ml - 1% DV Dec-18 to 2021	70 ml	Vfend
80	ETHAMBUTOL HYDROCHLORIDE (delisting) → Tab 100 mg48.01 Note – Myambutol tab 100 mg to be delisted from 1 February 2019.	56	Myambutol
MUSC	CULOSKELETAL SYSTEM		
102	NAPROXEN († price and addition of HSS) Tab 250 mg – 1% DV Dec-18 to 2021	500 250	Noflam 250 Noflam 500
NERV	OUS SYSTEM		
106	LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE (delisting) Inj 1%, 20 ml ampoule	1 1 n 1 February 20	Lidocaine-Claris Lidocaine-Claris 19.
108	MORPHINE HYDROCHLORIDE († price and addition of HSS) Oral liq 1 mg per ml – 1% DV Dec-18 to 2021	200 ml 200 ml 200 ml 200 ml	RA-Morph RA-Morph RA-Morph RA-Morph

	Price (ex man. Excl. 0 \$	GST) Per	Brand or Generic Manufacturer
Char	nges to Section H Part II – effective 1 October 2018 (continu	ued)	
117	GRANISETRON (new listing) Inj 1 mg per ml, 3 ml ampoule – 1% DV Dec-18 to 20200.40	1	Deva
119	LITHIUM CARBONATE (delisting) Tab 400 mg12.83 Note – Lithicarb FC tab 400 mg to be delisted from 1 March 2019.	100	Lithicarb FC
122	FINGOLIMOD (↓ price) → Cap 0.5 mg	28	Gilenya
124	ZOPICLONE (delist) Tab 7.5 mg	500 r 2018	Zopiclone Actavis
ONC	OLOGY AGENTS AND IMMUNOSUPPRESSANTS		
130	BLEOMYCIN SULPHATE († price and addition of HSS) Inj 15,000 iu vial – 1% DV Dec-18 to 2021 161.01	1	DBL Bleomycin Sulfate
131	AZACITIDINE (brand change) → Inj 100 mg vial – 1% DV Dec-18 to 2021139.00 Note – Vidaza inj 100 mg vial to be delisted from 1 December 2018.	1	Azacitdine Dr Reddy's
131	CYTARABINE (addition of HSS) Inj 100 mg per ml, 20 ml vial – 1% DV Dec-18 to 2021 41.36	1	Pfizer
140	RUXOLITINIB (new listing) → Tab 5 mg	56 56 56	Jakavi Jakavi Jakavi

- 2 A classification of risk of intermediate-2 or high-risk myelofibrosis according to either the International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or the Age-Adjusted DIPSS; and
- 3 A maximum dose of 20 mg twice daily is to be given.

Continuation

Haematologist

Reassessment required after 12 months

Roth.

- 1 The treatment remains appropriate and the patient is benefiting from treatment; and
- 2 A maximum dose of 20 mg twice daily is to be given.

Price	Brand or
(ex man. Excl. GST)	Generic
\$ Per	Manufacturer

Changes to Section H Part II – effective 1 October 2018 (continued)

145 TACROLIMUS (HSS removed. 1 price and amended restriction)

→ Cap 0.5 mg – 1% DV Nov-14 to 31 Oct 2018 30 Sep 2018 55.64	100	Tacrolimus Sandoz
→ Cap 1 mg – 1% DV Nov-14 to 31 Oct 2018 30 Sep 2018 111.28	100	Tacrolimus Sandoz
→ Cap 5 mg – 1% DV Nov-14 to 31 Oct 2018 30 Sep 2018 278.20	50	Tacrolimus Sandoz

→ Inj 5 mg per ml, 1 ml ampoule

Restricted

Initiation - organ transplant recipients

Any specialist

For use in organ transplant recipients.

Initiation – non-transplant indications*

Any specialist

Roth:

- 1 Patient requires long-term systemic immunosuppression; and
- 2 Ciclosporin has been trialled and discontinued treatment because of unacceptable side effects or inadequate clinical response.

Note: Indications marked with * are unapproved indications

Initiation - Steroid-resistant nephrotic syndrome*

Anv specialist

Either:

- 1 The patient is a child with steroid-resistant nephrotic syndrome* (SRNS) where ciclosporin has been trialled-in combination with prednisone and discontinued because of unacceptable side effects or inadequate clinical response; or
- 2 All of the following:
 - 2.1 The patient is an adult with SRNS; and
 - 2.2 Ciclosporin has been trialled in combination with prednisone and discontinued because of unacceptableside effects or inadequate clinical response; and
 - 2.3 Cyclophosphamide or mycophenolate have been trialled and discontinued because of unacceptable side effects or inadequate clinical response, or these treatments are contraindicated.

Note: Indications marked with * are unapproved indications

159	BASILIXIMAB (↓ price) → Inj 20 mg vial2,56	30.00	1	Simulect
166	OMALIZUMAB (new listing) → Inj 150 mg prefilled syringe45	50.00	1	Xolair

Price		Brand or
(ex man. Excl.	GST)	Generic
\$	Per	Manufacturer

Changes to Section H Part II - effective 1 October 2018 (continued)

166 OMALIZUMAB (‡ price and amended restriction)

Initiation - severe asthma

Clinical immunologist or respiratory specialist

Reassessment required after 6 months

All of the following:

- 1 Patient must be aged 6 years or older Patient is over the age of 6; and
- 2 Patient has a diagnosis of severe, life threatening asthma; and
- 3 Past or current evidence of atopy, documented by skin prick testing or RAST; and
- 4 Total serum human immunoglobulin E (IgE) between 76 IU/mL and 1300 IU/ml at baseline; and
- 5 Proven compliance-adherence with optimal inhaled therapy including high dose inhaled corticosteroid (budesonide 1,600 mcg-micrograms per day or fluticasone propionate 1,000 mcg-micrograms per day or equivalent), plus long-acting beta-2 agonist therapy (at least salmeterol 50 mcg-micrograms bd) or eformoterol 12 mcg-micrograms bd) for at least 12 months, unless contraindicated or not tolerated; and
- 6 Either:
 - 6.1 Patient has received courses of systemic corticosteroids equivalent to at least 28 days treatment in the past 12 months, unless contraindicated or not tolerated; and or
 - 6.2 7. At least four admissions to hospital for a severe asthma exacerbation over the previous 24 months with at least one of those being in the previous 12 months; and Patient has had at least 4 exacerbations needing systemic corticosteroids in the previous 12 months, where an exacerbation is defined as either documented use of oral corticosteroids for at least 3 days or parenteral steroids; and
- 8 An Asthma Control Questionnaire (ACQ-5) score of at least 3.0 as assessed in the previous month.
- 7 Patient has an Asthma Control Test (ACT) score of 10 or less; and
- 8 Baseline measurements of the patient's asthma control using the ACT and oral corticosteroid dose must be made at the time of application, and again at around 26 weeks after the first dose to assess response to treatment.

Continuation - severe asthma

Respiratory specialist

Reassessment required after 6 months

Both:

- 1 Hospital admissions have been reduced as a result of treatment; and
- 1 A reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 1.0 from baseline An increase in the Asthma Control Test (ACT) score of at least 5 from baseline; and
- 2 A reduction in the maintenance oral corticosteroid dose or number of exacerbations of at least 50% from baseline

Initiation - severe chronic spontaneous urticaria

Clinical immunologist or dermatologist

Reassessment required after 6 months

All of the following:

- 1 Patient must be aged 12 years or older; and
- 2 Either:
 - 2.1 Both:
 - 2.1.1 Patient is symptomatic with Urticaria Activity Score 7 (UAS7) of 20 or above; and
 - 2.1.2 Patient has a Dermatology life quality index (DLQI) of 10 or greater; or
 - 2.2 Patient has a Urticaria Control Test (UCT) of 8 or less; and
- 3 Any of the following:
 - 3.1 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and ciclosporin (>3 mg/kg day) for at least 6 weeks; or

continued...

Price (ex man. Excl. GST) \$ Per Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 October 2018 (continued)

- 3.2 Patient has been taking high dose antihistamines (e.g. 4 times standard dose) and at least 3 courses of systemic corticosteroids (>20 mg prednisone per day for at least 5 days) in the previous 6 months; or
- 3.3 Patient has developed significant adverse effects whilst on corticosteroids or ciclosporin; and
- 4 Either:
 - 4.1 Treatment to be stopped if inadequate response* following 4 doses; or
 - 4.2 Complete response* to 6 doses of omalizumab.

Continuation - severe chronic spontaneous urticaria

Clinical immunologist or dermatologist

Reassessment required after 6 months

Either:

- 1 Patient has previously adequately responded* to 6 doses of omalizumab; or
- 2 Both
 - 2.1 Patient has previously had a complete response* to 6 doses of omalizumab; and
 - 2.2 Patient has relapsed after cessation of omalizumab therapy.

Note: *Inadequate response defined as less than 50% reduction in baseline UAS7 and DLQI score, or an increase in Urticaria Control Test (UCT) score of less than 4 from baseline. Patient is to be reassessed for response after 4 doses of omalizumab. Complete response is defined as UAS7 less than or equal to 6 and DLQI less than or equal to 5; or UCT of 16. Relapse of chronic urticaria on stopping prednisone/ciclosporin does not justify the funding of omalizumab.

176 SECUKINUMAB (new listing)

→Inj 150 mg per ml, 1 ml prefilled syringe.......1,599.00 2 Cosentyx

Restricted

Initiation - severe chronic plaque psoriasis, second-line biologic

Dermatologist

Reassessment required after 4 months

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab or etanercept, or has trialled infliximab in a DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule, for severe chronic plaque psoriasis; and
- 2 Either:
 - 2.1 The patient has experienced intolerable side effects from adalimumab, etanercept or infliximab; or
 - 2.2 The patient has received insufficient benefit from adalimumab, etanercept or infliximab; and
- 3 A Psoriasis Area and Severity Index (PASI) assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Continuation - severe chronic plaque psoriasis, second-line biologic

Dermatologist

Reassessment required after 6 months

Both:

- 1 Either
 - 1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
 - 1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

continued...

→ Restriction

Price Brand or (ex man. Excl. GST) Generic \$ Per Manufacturer

Changes to Section H Part II - effective 1 October 2018 (continued)

continued...

Initiation - severe chronic plaque psoriasis, first-line biologic

Dermatologist

Reassessment required after 4 months

All of the following:

- 1 Fither:
 - 1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis; or
 - 1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
- 2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
- 3 A PASI assessment or Dermatology Quality of Life Index (DLQI) assessment has been completed for at least the most recent prior treatment course, preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
- 4 The most recent PASI or DQLI assessment is no more than 1 month old at the time of application.

Note: A treatment course is defined as a minimum of 12 weeks of treatment. "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom sub scores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Continuation - severe chronic plaque psoriasis, first-line biologic Dermatologist

Reassessment required after 6 months

Both:

- 1 Either
 - 1.1 Patient's PASI score has reduced by 75% or more (PASI 75) as compared to baseline PASI prior to commencing secukinumab; or
 - 1.2 Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing secukinumab; and
- 2 Secukinumab to be administered at a maximum dose of 300 mg monthly.

Price (ex man. Excl. GST) \$ Pe Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 October 2018 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

187 TIOTROPIUM BROMIDE (restriction removed)

Note: tiotropium treatment must not be used if the patient is also receiving treatment with subsidised inhaled alvcopyrronium or umeclidinium.

Restricted

Initiation

All of the following:

- 1 To be used for the long-term maintenance treatment of bronchospasm and dyspnoea associated with COPD; and
- 2 In addition to standard treatment, the patient has trialled a short acting bronchodilator dose of at least 40 μg-ipratropium q.i.d for one month; and
- 3 Fither:

the patient's breathlessness according to the Medical Research Council (UK) dyspnoea scale is:

- 3.1 Grade 3 (stops for breath after walking about 100 meters or after a few minutes on the level); or
- 3.2 Grade 4 (too breathless to leave the house, or breathless when dressing or undressing); and
- 4 Actual FEV1 as a % of predicted, must be below 60%; and
- 5 Either:
 - 5.1 Patient is not a smoker (for reporting purposes only); or
 - 5.2 Patient is a smoker and has been offered smoking cessation counselling; and
- 6 The patient has been offered annual influenza immunization.

188 NINTEDANIB (new listing)

	\	3/		
→	Cap 100 mg	2,554.00	60	Ofev
→	Cap 150 mg	3,870.00	60	Ofev

Restricted

Initiation - idiopathic pulmonary fibrosis

Respiratory specialist

Reassessment required after 12 months

All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 90% predicted; and
- 3 Nintedanib is to be discontinued at disease progression (See Note); and
- 4 Nintedanib is not to be used in combination with subsidised pirfenidone; and
- 5 Any of the following:
 - 5.1 The patient has not previously received treatment with pirfenidone; or
 - 5.2 Patient has previously received pirfenidone, but discontinued pirfenidone within 12 weeks due to intolerance: or
 - 5.3 Patient has previously received pirfenidone, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with pirfenidone).

Continuation - idiopathic pulmonary fibrosis

Respiratory specialist

Reassessment required after 12 months

All of the following:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Nintedanib is not to be used in combination with subsidised pirfenidone; and

continued...

Price		Brand or
(ex man. Excl. G	ST)	Generic
 \$	Per	Manufacturer

Changes to Section H Part II - effective 1 October 2018 (continued)

continued...

3 Nintedanib is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

188 PIRFENIDONE (amended restriction criteria)

Restricted

Initiation - idiopathic pulmonary fibrosis

Respiratory specialist

Reassessment required after 12 months

All of the following:

- 1 Patient has been diagnosed with idiopathic pulmonary fibrosis as confirmed by histology, CT or biopsy by a multidisciplinary team including a radiologist; and
- 2 Forced vital capacity is between 50% and 80% predicted; and
- 3 Pirfenidone is to be discontinued at disease progression (See Notes); and
- 4 Pirfenidone is not to be used in combination with subsidised nintedanib; and
- 5 Any of the following:
 - 5.1 The patient has not previously received treatment with nintedanib; or
 - 5.2 Patient has previously received nintedanib, but discontinued nintedanib within 12 weeks due to intolerance; or
 - 5.3 Patient has previously received nintedanib, but the patient's disease has not progressed (disease progression defined as 10% or more decline in predicted FVC within any 12 month period since starting treatment with nintedanib).

Continuation - idiopathic pulmonary fibrosis

Respiratory specialist

Reassessment required after 12 months

All of the following Both:

- 1 Treatment remains clinically appropriate and patient is benefitting from and tolerating treatment; and
- 2 Pirfenidone is not to be used in combination with subsidised nintedanib; and
- 3 Pirfenidone is to be discontinued at disease progression (See Note).

Note: disease progression is defined as a decline in percent predicted FVC of 10% or more within any 12 month period.

VARIOUS

199 FLUMAZENIL (brand change)

Inj 0.1 mg per ml, 5 ml ampoule – **1% DV Dec-18 to 2021**..... 66.34 5 **HameIn** Note – Anexate inj 0.1 mg per ml, 5 ml ampoule to be delisted from 1 December 2018.

SPECIAL FOODS

- 214 AMINO ACID FORMULA (WITHOUT PHENYLALANINE) (delisting)
 - → Powder 25 g protein and 51 g carbohydrate per 100 g,

500 g can e.g. XP Maxamaid

Note – Amino acid formula (without phenylalanine) (e.g. XP Maxamaid) powder, 500 g can to be delisted 1 April 2019.

Price (ex man. Excl. GST) \$ Pel Brand or Generic Manufacturer

Changes to Section H Part II – effective 1 September 2018

ALIMENTARY	TRACT	VND	METABOLISM
ALIMENIANI	INAUI	MINU	MICIADULISM

17	MAGNESIUM CHLORIDE (new listing)
	Inj 1 mmol per 1 ml, 100 ml bag

20	THIAMINE HYDROCHLORIDE (new listing)			
	Tab 50 mg - 1% DV Nov-18 to 2020	4.89	100	Max Health

BLOO	D AND BLOOD FORMING ORGANS		
28	HEPARIN SODIUM (↓ price and addition of HSS) Inj 1,000 iu per ml, 5 ml ampoule — 1% DV Nov-18 to 2021	50	Pfizer
	- 1% DV Nov-18 to 2021203.68	50	Pfizer
28	RIVAROXABAN (delisting) Tab 10 mg41.55 Note – Xarelto tab 10 mg, 15 tab pack to be delisted from 1 December 2018	15	Xarelto
29	EPTIFIBATIDE († price and addition of HSS) → Inj 2 mg per ml, 10 ml vial – 1% DV Nov-18 to 2021138.75 → Inj 750 mcg per ml, 100 ml vial – 1% DV Nov-18 to 2021405.00	1	Integrilin Integrilin
33	COMPOUND ELECTROLYTES WITH GLUCOSE [DEXTROSE] (new listing, am presentation description) Soln with electrolytes (2 x 500 ml) – 1% DV Nov-18 to 2021 6.55	nended che 1,000 ml	mical name and Pedialyte – Bubblegum

CARDIOVASCULAR SYSTEM

35	QUINAPRIL († price and addition of HSS) Tab 5 mg – 1% DV Nov-18 to 2021 Tab 10 mg – 1% DV Nov-18 to 2021		90 90	Arrow-Quinapril 5 Arrow-Quinapril 10
35	QUINAPRIL (‡ price and addition of HSS) Tab 20 mg – 1% DV Nov-18 to 2021	4.89	90	Arrow-Quinapril 20
40	VERAPAMIL HYDROCHLORIDE (Pharmacode change) Inj 2.5 mg per ml, 2 ml ampoule			Isoptin from 1 March 2019.

44 ISOPRENALINE [ISOPROTERENOL] (amended chemical name)

Inj 200 mcg per ml, 1 ml ampoule

Inj 200 mcg per ml, 5 ml ampoule

Price		Brand or
(ex man. Excl. GST)		Generic
\$	Per	Manufacturer

Changes to Section H Part II – effective 1 September 2018 (continued)

- 46 SILDENAFIL (amended restriction affected criteria shown only)

 - → Inj 0.8 mg per ml, 12.5 ml vial

Restricted

Initiation - tablets Pulmonary arterial hypertension

Any of the following:

- 1 All of the following:
 - 1.1 Patient has pulmonary arterial hypertension (PAH)*; and
 - 1.2 Any of the following:
 - 1.2.1 PAH is in Group 1 of the WHO (Venice) clinical classifications; or
 - 1.2.2 PAH is in Group 4 of the WHO (Venice) clinical classifications, or
 - 1.2.3 PAH is in Group 5 of the WHO (Venice) clinical classifications; and
 - 1.3 Any of the following:
 - 1.3.1 PAH is in NYHA/WHO functional class II: or
 - 1.3.2 PAH is in NYHA/WHO functional class III; or
 - 1.3.3 PAH is in NYHA/WHO functional class IV; and
 - 1.4 Either:

1.4.1 All of the following:

- 1.4.1.1 1.4 Patient has a pulmonary capillary wedge pressure (PCWP) less than or equal to 15 mmHo: and
- 1.4.1.2 1.5 Either:
 - **1.4.1.2.1** $\frac{1.5.1}{0.00}$ Patient has a mean pulmonary artery pressure (PAPm) > 25 mmHg; or
 - 1.4.2.2.2 1.5.2 Patient is peri Fontan repair; and
- 1.4.1.3 1-6 Patient has a pulmonary vascular resistance (PVR) of at least 3 Wood Units or at least 240 International Units (dyn s cm-5); or

1.4.2 Testing for PCWP, PAPm, or PVR cannot be performed due to the patient's young age; or

- 2 For use in neonatal units for persistent pulmonary hypertension of the newborn (PPHN); or
- 3 In-hospital stabilisation in emergency situations

DERMATOLOGICALS

50	CALAMINE (brand change) Crm, aqueous, BP – 1% DV Nov-18 to 2021	.1.26	100 g	healthE Calamine Aqueous Cream BP
	Note – Pharmacy Health crm, aqueous, BP to be delisted from 1 $^{\rm N}$	lovember 2	2018.	·
52	MOMETASONE FUROATE (addition of HSS)			
	Crm 0.1% – 1% DV Nov-18 to 2021	. 1.51	15 g	Elocon Alcohol Free
	Oint 0.1% - 1% DV Nov-18 to 2021	. 1.51	15 g	Elocon
		2.90	50 g	Elocon
52	MOMETASONE FUROATE (‡ price and addition of HSS)			
	Crm 0.1% – 1% DV Nov-18 to 2021	.2.50	50 g	Elocon Alcohol Free
	Lotn 0.1% – 1% DV Nov-18 to 2021	. 6.30	30 ml	Elocon

Price		Brand or
(ex man. Excl. G	ST)	Generic
\$	Per	Manufacturer

Changes to Section H Part II - effective 1 September 2018 (continued)

GENITO-URINARY SYSTEM

57	OXYTOCIN (‡ price and addition of HSS)		
	Inj 5 iu per ml, 1 ml ampoule – 1% DV Nov-18 to 2021 3.98	5	Oxytocin BNM
	Inj 10 iu per ml, 1 ml ampoule – 1% DV Nov-18 to 2021 4.98	5	Oxytocin BNM

HORMONE PREPARATIONS

60	CALCITONIN (Pharmacode change) Inj 100 iu per ml, 1 ml ampoule Note – this is a new Pharmacode listing, 2548356. Pharmacode	5 delisted fro	Miacalcic om 1 March 2019.
60	TESTOSTERONE UNDECANOATE († price and addition of HSS) Cap 40 mg – 1% DV Nov-18 to 2021	60	Andriol Testocaps

INFECTIONS

75 MOXIFLOXACIN (amended restriction – affected criteria shown only)

-	Tab 400 mg	52.00	5	Avelox
-	Inj 1.6 mg per ml, 250 ml bottle	70.00	1	Avelox IV 400

Restricted

Initiation – Mycobacterium infection

Infectious disease specialist, clinical microbiologist or respiratory specialist

Any of the following Either:

- 1 Both:
 - 1.1 Active tuberculosis; and
 - 1.2 Any of the following:
 - 1.2.1 Documented resistance to one or more first-line medications; or
 - 1.2.2 Suspected resistance to one or more first-line medications (tuberculosis assumed to be contracted in an area with known resistance), as part of regimen containing other second-line agents; or
 - 1.2.3 Impaired visual acuity (considered to preclude ethambutol use); or
 - 1.2.4 Significant pre-existing liver disease or hepatotoxicity from tuberculosis medications; or
 - 1.2.5 Significant documented intolerance and/or side effects following a reasonable trial of first-line medications; or
- 2 Mycobacterium avium-intracellulare complex not responding to other therapy or where such therapy is contraindicated; or
- 3 Patient is under five years of age and has had close contact with a confirmed multi-drug resistant tuberculosis case.

Initiation - Mycoplasma genitalium

All of the following:

- 1 Has nucleic acid amplification test (NAAT) confirmed Mycoplasma genitalium and is symptomatic; and
- 2 Either:
 - 2.1 Has tried and failed to clear infection using azithromycin; and or
 - 2.2 Has laboratory confirmed azithromycin resistance; and
- 3 Treatment is only for 7 days.

Price		Brand or
(ex man. Excl. G	iST)	Generic
\$	Per	Manufacturer

Changes to Section H Part II – effective 1 September 2018 (continued)

85 RITONAVIR (delisting)

→ Oral lig 80 mg per ml

Note – Ritonavir oral liq 80 mg per ml to be delisted from 1 September 2018.

NERVOUS SYSTEM

106	LIDOCAINE [LIGNOCAINE] HYDROCHLORIDE († price, addition of HSS and	d amended un	it of measure)
	Gel 2% – 1% DV Nov-18 to 2021	20 g ml	Orion
107	PARACETAMOL (addition of HSS)		
	Suppos 125 mg – 1% DV Nov-18 to 2021 (\dagger price)3.29	10	Gacet
	Suppos 250 mg – 1% DV Nov-18 to 2021 3.79	10	Gacet
108	FENTANYL (‡ price and addition of HSS)		
	Inj 50 mcg per ml, 2 ml ampoule – 1% DV Nov-18 to 2021 3.56	10	Boucher and Muir
	Inj 50 mcg per ml, 10 ml ampoule – 1% DV Nov-18 to 2021 9.41	10	Boucher and Muir
112	ETHOSUXIMIDE (new listing)		
	Cap 250 mg281.75	200	Zarontin
	Oral liq 50 mg per ml56.35	200 ml	Zarontin
117	PROMETHAZINE THEOCLATE (delisting)		
	→ Tab 25 mg		
	Note – Promethazine theoclate tab 25 mg to be delisted from 1 December	2018.	

ONCOLOGY AGENTS AND IMMUNOSUPPRESSANTS

	Inj 50 mg per ml, 50 ml vial Note – Fluorouracil Ebewe inj 50 mg per ml, 50 ml vial			Fluorouracil Ebewe 9.
135	TEMOZOLOMIDE (amended restriction – affected criteri	a shown only)		
	→ Cap 5 mg – 1% DV Feb-17 to 2019	10.20	5	Orion Temozolomide
	→ Cap 20 mg – 1% DV Feb-17 to 2019	18.30	5	Orion Temozolomide

Restricted

131

Initiation - Ewing's Sarcoma

FLUOROURACIL (delisting)

Reassessment required after 9 months

Patient has relapse or refractory Ewing's sarcoma.

Continuation - Ewing's Sarcoma

Reassessment required after 6 months

Both:

- 1 No evidence of disease progression; and
- 2 The treatment remains appropriate and the patient is benefitting from treatment.

5

Orion Temozolomide

Orion Temozolomide

Price	Brand or
(ex man. Excl. GST)	Generic
\$ Per	Manufacturer

Changes to Section H Part II – effective 1 September 2018 (continued)

144	LETROZOLE († price and addition of HSS) Tab 2.5 mg – 1% DV Nov-18 to 2021	30	Letrole
151	ADALIMUMAB (amended restrctions – affected criteria shown only)		
	→ Inj 20 mg per 0.4 ml syringe	2	Humira
	→ Inj 40 mg per 0.8 ml pen	2	HumiraPen
	→ Inj 40 mg per 0.8 ml syringe	2	Humira

Restricted

Initiation - Crohn's disease - adults

Gastroenterologist

Re-assessment required after 3 months

All of the following:

- 1 Patient has severe active Crohn's disease; and
- 2 Any of the following:
 - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
 - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
 - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection: or
 - 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

Continuation - Crohn's disease - adults

Gastroenterologist

Re-assessment required after 3 months

Roth:

- 1 Either:
 - 1.1 Either:
 - 1.1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
 - 1.1.2 CDAI score is 150 or less: or
 - 1.2 Both:
 - 2.2.1 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
 - $2.2.2\,\,$ Applicant to indicate the reason that CDAI score cannot be assessed; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Initiation - Crohn's disease - children

Gastroenterologist

Re-assessment required after 3 months

All of the following:

- 1 Paediatric patient has severe active Crohn's disease; and
- 2 Either:
 - 2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
 - 2.2 Patient has extensive small intestine disease: and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

continued...

Price		Brand or
(ex man. Excl.	GST)	Generic
\$	Per	Manufacturer

Changes to Section H Part II - effective 1 September 2018 (continued)

continued...

Continuation - Crohn's disease - children

Gastroenterologist

Re-assessment required after 3 months

Both:

- 1 Any of the following:
 - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
 - 1.2 PCDAI score is 15 or less: or
 - 1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
- 2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

RESPIRATORY SYSTEM AND ALLERGIES

186	FLUTICASONE PROPIONATE (4 price and addition of HSS) Nasal spray 50 mcg per dose – 1% DV Nov-18 to 2021	120 dose	Flixonase Hayfever & Allergy
188	SALBUTAMOL († price and addition of HSS) Oral liq 400 mcg per ml – 1% DV Nov-18 to 202120.00	150 ml	Ventolin

SPECIAL FOODS

- 223 ENTERAL FEED 1.5 KCAL/ML (delisting)
 - → Liquid 5.4 g protein, 13.6 g carbohydrate and 3.3 g fat per 100 ml,1,000 ml bottle

e.g. Isosource Standard RTH

Note – Enteral feed 1.5 kcal/ml (e.g. Isosource Standard RTH) liquid, 1,000 ml bottle to be delisted 1 September 2018.

Price (ex man. Excl. GST) \$ Po Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 August 2018

ALIMENTARY TRACT AND METABOLISM

5	ALUMINIUM HYDROXIDE WITH MAGNESIUM HYDROXIDE AND SIMETICONE SIMETHICONE (amended chemical
	name and presentation description)

Tab 200 mg with magnesium hydroxide 200 mg and

simeticone simethicone 20 mg

e.a. Mvlanta

Oral liq 400 mg with magnesium hydroxide 400 mg and simeticone simethicone 30 mg per 5 ml

e.g. Mylanta Double Strenath

5 **SIMETICONE** SIMETHICONE (amended chemical name)

Oral drops 100 mg per ml

5 SIMETICONE (new listing)

Oral drops 20 mg per 0.3 ml

ew listing)
l

10 PIOGLITAZONE (addition of HSS)

Tab 15 mg – 1% DV Oct-18 to 2021	90	Vexazone
Tab 30 mg – 1% DV Oct-18 to 2021 5.06	90	Vexazone
Tab 45 mg – 1% DV Oct-18 to 2021	90	Vexazone

12 GLYCEROL († price and addition of HSS)

- 15 IMIGLUCERASE (delisting)
 - → Inj 40 iu per ml, 5 ml vial
 - → Ini 40 iu per ml. 10 ml vial

Note – Imiglucerase inj 40 iu per ml, 5 ml and 10 ml vials to be delisted from 1 March 2019.

16 TALIGLUCERASE ALFA (new listing)

Restricted

Initiation

Only for use in patients with approval by the Gaucher's Treatment Panel.

17 FERROUS SULPHATE (Pharmacode change)

Tab long-acting 325 mg (105 mg elemental)

- 1% DV Jun-18 to 2021......2.06 30 Ferrograd

Note – this is a new Pharmacode listing, 2534819. 604321 to be delisted from 1 February 2019.

BLOOD AND BLOOD FORMING ORGANS

23 FOLIC ACID († price and addition of HSS)

1ab 0.6 mg - 1% by 0ci-16 to 202121.04	1,000	Apo-rolic Acid
Tab 5 mg – 1% DV Oct-18 to 2021 12.12	500	Apo-Folic Acid

04 04

4 000

Acces Falls Askets

	Pric (ex man. E \$	xcl. GST) Per	Brand or Generic Manufacturer
Cha	nges to Section H Part II – effective 1 August 2018 (con	tinued)		
25	TRANEXAMIC ACID (pack size correction) Inj 100 mg per ml, 10 ml ampoule – 1% DV Sep-18 to 2021 10.8 Note – this is a correction to the pack size only.	95	5 10	Tranexamic-AFT
28	RIVAROXABAN (4 price and restriction removed) Tab 10 mg	55	15	Xarelto
	Initiation — total hip replacement Limited to 5 weeks treatment For the prophylaxis of venous thromboembolism.			
	Initiation — total knee replacement <u>Limited to 2 weeks treatment</u> For the prophylaxis of venous thromboembolism.			
28	RIVAROXABAN (new listing)	56	30 28 28	Xarelto Xarelto Xarelto
33	SODIUM DIHYDROGEN PHOSPHATE [SODIUM ACID PHOSPHATE] († Inj 1 mmol per ml, 20 ml ampoule – 1% DV Oct-18 to 2021 48.7		nd additio	on of HSS) Biomed
33	POTASSIUM CHLORIDE († price and addition of HSS) Tab long-acting 600 mg (8 mmol) – 1% DV Oct-18 to 2021 8.5	90	200	Span-K
CAR	DIOVASCULAR SYSTEM			
35	TRANDOLAPRIL (delisting) → Cap 1 mg → Cap 2 mg Note – Trandolapril cap 1 mg and 2 mg to be delisted from 1 January	2019.		
35	ENALAPRIL MALEATE WITH HYDROCHLOROTHIAZIDE (delisting) → Tab 20 mg with hydrochlorothiazide 12.5 mg Note — Enalapril maleate with hydrochlorothiazide tab 20 mg with hydrom 1 January 2019.	rochloro	thiazide [·]	12.5 mg to be delisted
37	ATROPINE SULPHATE (brand change) Inj 600 mcg per ml, 1 ml ampoule – 1% DV Oct-18 to 2021 12.0 Note – AstraZeneca inj 600 mcg per ml, 1 ml ampoule to be delisted f		10 ctober 2	Martindale 018.
38	METOPROLOL TARTRATE (brand change) Inj 1 mg per ml, 5 ml vial – 1% DV Feb-19 to 31 Jan 2022 29.5 Note – Lopresor inj 1 mg per ml, 5 ml vial to be delisted from 1 Februa		5 9.	Metoprolol IV Mylan
38	METOPROLOL TARTRATE († price and addition of HSS) Tab 50 mg – 1% DV Oct-18 to 2021		100 60	Apo-Metoprolol Apo-Metoprolol

		Price (ex man. Excl. G		Brand or Generic
		\$	Per	Manufacturer
Char	iges to Section H Part II – effective 1 August	2018 (continue	d)	
38	NADOLOL († price and addition of HSS) Tab 40 mg – 1% DV Oct-18 to 2021 Tab 80 mg – 1% DV Oct-18 to 2021		100 100	Apo-Nadolol Apo-Nadolol
38	PINDOLOL († price and addition of HSS) Tab 5 mg – 1% DV Oct-18 to 2021 Tab 10 mg – 1% DV Oct-18 to 2021 Tab 15 mg – 1% DV Oct-18 to 2021	23.12	100 100 100	Apo-Pindolol Apo-Pindolol Apo-Pindolol
38	PROPRANOLOL († price and addition of HSS) Tab 10 mg – 1% DV Oct-18 to 2021 Tab 40 mg – 1% DV Oct-18 to 2021		100 100	Apo-Propranolol Apo-Propranolol
39	ISRADIPINE (delisting) Cap long-acting 2.5 mg Cap long-acting 5 mg Note – Isradipine cap long-acting 2.5 mg and 5 mg to be	e delisted from 1 Oc	tober 2018	
39	DILTIAZEM HYDROCHLORIDE († price and addition of H: Cap long-acting 120 mg – 1% DV Oct-18 to 2021 Cap long-acting 180 mg – 1% DV Oct-18 to 2021 Cap long-acting 240 mg – 1% DV Oct-18 to 2021	33.42 50.05	500 500 500	Apo-Diltiazem CD Apo-Diltiazem CD Apo-Diltiazem CD
39	NIFEDIPINE (HSS suspended) Tab long-acting 30 mg – 1% DV Dec-17 to 31 Jul 18	2020 3.14	30	Adalat Oros
40	VERAPAMIL HYDROCHLORIDE (Pharmacode change) Tab 80 mg Note – this is a listing of a new Pharmacode, 2535335. I		100 2 to be deli	Isoptin sted from 1 July 2019.
40	CLONIDINE HYDROCHLORIDE (‡ price and addition of H Tab 25 mcg – 1% DV Oct-18 to 2021		112	Clonidine BNM
40	CLONIDINE HYDROCHLORIDE (brand change) Inj 150 mcg per ml, 1 ml ampoule – 1% DV Oct-18 to Note – Catapres inj 150 mcg per ml, 1 ml ampoule to be		10 tober 2018.	Medsurge
43	DOBUTAMINE HYDROCHLORIDE (brand change) Inj 12.5 mg per ml, 20 ml ampoule Note – Dobutamine-hameln inj 12.5 mg per ml, 20 ml ar		5 d from 1 Ja	Dobutamine-hameln nuary 2019.
45	BOSENTAN (brand change) → Tab 62.5 mg – 1% DV Dec-18 to 2021 → Tab 125 mg – 1% DV Dec-18 to 2021 Note – Bosentan-Mylan tab 62.5 mg and 125 mg to be compared to the second	141.00	60 60 ember 2018	Bosentan Dr Reddy's Bosentan Dr Reddy's
DERI	MATOLOGICALS			
50	ISOTRETINOIN (new listing) Cap 5 mg – 1% DV Oct-18 to 2021	8.14	60	Oratane

		Price (ex man. Excl. (Brand or Generic	
		\$	Per	Manufacturer	
Cha	nges to Section H Part II – effective 1 August 2	018 (continu	ed)		
50	ISOTRETINOIN (1 price and addition of HSS)	10.04	100	0	
	Cap 10 mg – 1% DV Oct-18 to 2021 Cap 20 mg – 1% DV Oct-18 to 2021		120 120	Oratane Oratane	
50	ISOTRETINOIN (delisting)	40.47	400		
	Cap 10 mg Cap 20 mg		100 100	Isotane 10 Isotane 20	
	Note – Isotane 10 cap 10 mg and Isotane 20 cap 20 mg to	be delisted from	n 1 October 2	2018.	
51	AQUEOUS CREAM († price and addition of HSS)	1.05	100 ~	Dharmany Haalth	
	Crm 100 g – 1% DV Oct-18 to 2021	1.05	100 g	Pharmacy Health SLS-free	
	Note: DV limit applies to the pack sizes of 100 g or le	SS.			
52	BETAMETHASONE VALERATE († price and addition of HSS				
	Crm 0.1% – 1% DV Oct-18 to 2021 Oint 0.1% – 1% DV Oct-18 to 2021		50 g 50 g	Beta Cream Beta Ointment	
			55 g	2014 0	
3	BETAMETHASONE VALERATE (addition of HSS) Scalp app 0.1% – 1% DV Oct-18 to 2021	7.75	100 ml	Beta Scalp	
BEN	ITO-URINARY SYSTEM			·	
57	OXYTOCIN WITH ERGOMETRINE MALEATE († price and ac	Idition of HSS)			
-	Inj 5 iu with ergometrine maleate 500 mcg per ml,	,			
	1 ml ampoule – 1% DV Oct-18 to 2021	15.00	5	Syntometrine	
8	POTASSIUM CITRATE († price and addition of HSS)	24.22			
	→ Oral liq 3 mmol per ml – 1% DV Oct-18 to 2021	31.80	200 ml	Biomed	
10R	MONE PREPARATIONS				
31	DEXAMETHASONE († price and addition of HSS)				
	Tab 0.5 mg – 1% DV Oct-18 to 2021 Tab 4 mg – 1% DV Oct-18 to 2021	0.99 1 90	30 30	Dexmethsone Dexmethsone	
	-		00	DOMINGUISONO	
64	SOMATROPIN (↓ price and addition of HSS) → Inj 5 mg cartridge – 1% DV Oct-18 to 2021	34.88	1	Omnitrope	
	→ Inj 10 mg cartridge – 1% DV Oct-18 to 2021	69.75	1	Omnitrope .	
	→ Inj 15 mg cartridge – 1% DV Oct-18 to 2021	104.63	1	Omnitrope	
NFE	CTIONS				
1	MEROPENEM (brand change)				
	→ Inj 500 mg vial – 1% DV Oct-18 to 2020 → Inj 1 g vial – 1% DV Oct-18 to 2020		1	Meropenem Ranb Meropenem Ranb	
	Note – DBL Meropenem inj 500 mg and 1 g vial to be delis		ber 2018.	meropeneni nanu	

		Price		Brand or	
	(ex mai	1. Excl. 6 \$	SST) Per	Generic Manufacturer	
han	nges to Section H Part II – effective 1 August 2018 (continue	ed)		
71	CEFALEXIN († price and addition of HSS) Grans for oral liq 25 mg per ml – 1% DV Oct-18 to 2021 Grans for oral liq 50 mg per ml – 1% DV Oct-18 to 2021		100 ml 100 ml	Cefalexin Sandoz Cefalexin Sandoz	
4	FLUCLOXACILLIN (addition of HSS) Grans for oral liq 25 mg per ml – 1% DV Oct-18 to 2021 Grans for oral liq 50 mg per ml – 1% DV Oct-18 to 2021		100 ml	AFT	
5	(† price)		100 ml	AFT	
7	→ Inj 2 mg per ml, 100 ml bag – 1% DV Oct-18 to 2021 LINEZOLID (↓ price and addition of HSS)		10	Cipflox	
7	→ Tab 600 mg – 1% DV Oct-18 to 2021		10	Zyvox	
0	Tab 300 mg – 1% DV Oct-18 to 2021		50	TMP	
6	→ Tab 100 mg – 1% DV Oct-18 to 2021	22.00	100	PSM	
	Tab 0.5 mg – 1% DV Nov-18 to 2021 Note – Baraclude tab 0.5 mg to be delisted from 1 November 2018		30	Entecavir Sandoz	
/IUS	CULOSKELETAL SYSTEM				
14	ETIDRONATE DISODIUM (delisting) Tab 200 mg Note – Arrow-Etidronate tab 200 mg to be delisted from 1 January		100	Arrow-Etidronate	
00	BACLOFEN († price and addition of HSS) Tab 10 mg – 1% DV Oct-18 to 2021	.4.20	100	Pacifen	
01	DICLOFENAC SODIUM († price and addition of HSS) Tab EC 50 mg – 1% DV Oct-18 to 2021 Tab long-acting 75 mg – 1% DV Oct-18 to 2021		50 500	Diclofenac Sando Apo-Diclo SR	
01	DICLOFENAC SODIUM (4 price and addition of HSS) Tab EC 25 mg – 1% DV Oct-18 to 2021 Tab long-acting 100 mg – 1% DV Oct-18 to 2021		50 500	Diclofenac Sando Apo-Diclo SR	
02	MELOXICAM (delisting) → Tab 7.5 mg Note – Meloxicam tab 7.5 mg to be delisted from 1 November 201	8			
02	NAPROXEN († price and addition of HSS) Tab long-acting 750 mg – 1% DV Oct-18 to 2021 Tab long-acting 1 g – 1% DV Oct-18 to 2021		28 28	Naprosyn SR 750 Naprosyn SR 100	

Price		Brand or
(ex man. Excl. (GST)	Generic
 \$	Per	Manufacturer

Changes to Section H Part II - effective 1 August 2018 (continued)

NERVOUS SYSTEM

108	FENTANYL (pack size change) Inj 20 mcg per ml, 50 ml syringe – 1% DV Oct-18 to 2021 18.74 Note – Biomed inj 20 mcg per ml, 50 ml syringe, 10 pack to be delisted 1		Biomed
108	METHADONE HYDROCHLORIDE († price and addition of HSS) Oral liq 2 mg per ml – 1% DV Oct-18 to 2021	200 ml 200 ml 200 ml	Biodone Biodone Forte Biodone Extra Forte
110	CLOMIPRAMINE HYDROCHLORIDE († price and addition of HSS) Tab 10 mg – 1% DV Oct-18 to 2021	100 100	Apo-Clomipramine Apo-Clomipramine
111	MIRTAZAPINE († price and addition of HSS) Tab 30 mg – 1% DV Oct-18 to 2021	30 30	Apo-Mirtazapine Apo-Mirtazapine
112	GABAPENTIN (restriction removed and brands delisted) Note: Gabapentin not to be given in combination with pregabalin	100	Arrow Cohonontin
	Capsule 100 mg		Arrow-Gabapentin Neurontin Nupentin
	Capsule 300 mg11.00	100	Arrow-Gabapentin Neurontin Nupentin
	Capsule 400 mg13.75	100	Arrow-Gabapentin Neurontin Nupentin

Restricted

Initiation - preoperative and/or postoperative use

Limited to 8 days treatment

Initiation - pain management of burns patients

Re-assessment required after 1 month

Continuation - pain management of burns patients

Re-assessment required after 1 month

The treatment remains appropriate and the patient is benefiting from treatment.

Initiation - epilepsy

Re-assessment required after 15 months

Either:

- 1 Seizures are not adequately controlled with optimal treatment with other antiepilepsy agents; or
- 2 Seizures are controlled adequately but the patient has experienced unacceptable side effects from optimal-treatment with other antiepilepsy agents.

Note: "Optimal treatment with other antiepilepsy agents" is defined as treatment with other antiepilepsy agents-which are indicated and clinically appropriate for the patient, given in adequate doses for the patient's age, weight, and other features affecting the pharmacokinetics of the drug with good evidence of compliance.

Continuation - epilepsy

Patient has demonstrated a significant and sustained improvement in seizure rate or severity and/or quality of life.

continued...

Price (ex man. Excl. GST) \$ Per Brand or Generic Manufacturer

Changes to Section H Part II - effective 1 August 2018 (continued)

continued...

Note: As a guideline, clinical trials have referred to a notional 50% reduction in seizure frequency as an indicator of success with anticonvulsant therapy and have assessed quality of life from the patient's perspective

Initiation - Neuropathic pain or Chronic Kidney Disease-associated pruritus

Re-assessment required after 3 months

Either:

- 1 The patient has been diagnosed with neuropathic pain; or
- 2 Both:
 - 2.1 The patient has Chronic Kidney Disease Stage 5-associated pruritus* where no other cause for pruritusean be identified (e.g. scabies, allergy); and
 - 2.2 The patient has persistent pruritus not relieved with a trial of emollient/moisturising creams alone.

Continuation - Neuropathic pain or Chronic Kidney Disease-associated pruritus Either:

- 1 The patient has demonstrated a marked improvement in their control of pain or itch (prescriber determined); or
- 2 The patient has previously demonstrated clinical responsiveness to gabapentin and has now developed neuropathic pain in a new site.

Note: Indications marked with * are unapproved indications. Dosage adjustment of gabapentin is recommended for patients with renal impairment.

Note – Arrow-Gabapentin, Narontin and Nupentin brands of gabapentin cap 100 mg, 300 mg and 400 mg to be delisted 1 August 2018.

114	PHENOBARBITONE († price and addition of HSS) Tab 15 mg – 1% DV Oct-18 to 2021	500 500	PSM PSM
120	ZIPRASIDONE (HSS delayed) Cap 20 mg - 1% DV Sep-18 to 2021 14.50	60	Zusdone
120	OLANZAPINE (↓ price and addition of HSS) → Inj 210 mg vial – 1% DV Oct-18 to 2021	1 1 1	Zyprexa Relprevv Zyprexa Relprevv Zyprexa Relprevv
124	DEXAMFETAMINE SULFATE († price and addition of HSS) → Tab 5 mg – 1% DV Oct-18 to 202120.00	100	PSM
ONCO	DLOGY AGENTS AND IMMUNOSUPPRESSANTS		
130	CYCLOPHOSPHAMIDE († price and addition of HSS) Inj 1 g vial – 1% DV Oct-18 to 2021	1 1	Endoxan Endoxan
	CYCLOPHOSPHAMIDE († price and addition of HSS) Inj 1 g vial – 1% DV Oct-18 to 2021 35.65	1 1 1 1	

Price		Brand or
(ex man. Excl. 0	GST)	Generic
\$	Per	Manufacturer

Changes to Section H Part II – effective 1 August 2018 (continued)

RESPIRATORY SYSTEM AND ALLERGIES

186	BUDESONIDE (brand change) Nasal spray 50 mcg per dose – 1% DV Oct-18 to 2020	200 dose	
186	SALBUTAMOL WITH IPRATROPIUM BROMIDE († price and addition of HS Nebuliser soln 2.5 mg with ipratropium bromide 0.5 mg per 2.5 ml ampoule – 1% DV Oct-18 to 2021 5.20	20	Duolin
188	SALBUTAMOL († price and addition of HSS) Nebuliser soln 1 mg per ml, 2.5 ml ampoule - 1% DV Oct-18 to 2021	20 20	Asthalin Asthalin
191	BERACTANT (delisting) Soln 200 mg per 8 ml vial	1 2019.	Survanta
SENS	ORY ORGANS		
192	SODIUM FUSIDATE [FUSIDIC ACID] († price) Eve drops 1%	5 a	Fucithalmic

Index

Pharmaceuticals and brands

A		Biodone Extra Forte	
Accuretic 10	8	Biodone Forte	29
Accuretic 20	8	2.00, 0 04	
Adalat Oros	26	Bosentan	26
Adalimumab	22	Bosentan Dr Reddy's	26
Alprostadil hydrochloride	8	Budesonide	31
Aluminium hydroxide with		C	
magnesium hydroxide and simethicone	24	Calamine	19
Aluminium hydroxide with		Calcitonin	20
magnesium hydroxide and simeticone	24	Cefalexin	28
Amino acid formula (without phenylalanine)	17	Cefalexin Sandoz	28
Andriol Testocaps	20	Cipflox	28
Apo-Clomipramine	29	Ciprofloxacin	
Apo-Diclo SR		Clomipramine hydrochloride	
Apo-Diltiazem CD		Clonidine BNM	
Apo-Folic Acid		Clonidine hydrochloride	
Apo-Megestrol		Compound electrolytes with glucose [dextrose]	
Apo-Metoprolol	25	Cosentyx	
Apo-Mictoprolof		Cyclophosphamide	
Apo-Nadolol		Cyproterone acetate	
Apo-Pindolol		Cytarabine	
·		D	11
Apo-Propranolol		Daivobet	0
Aqueous cream			
		Daonil DBL Bleomycin Sulfate	
Arrow-Gabapentin			
Arrow-Quinapril 5		Depo-Medrol	
Arrow-Quinapril 10		Dexamethasone	
Arrow-Quinapril 20		Dexamfetamine sulfate	
Asthalin	31	Dexmethsone	
Atropine sulphate		Dextrose	
Avelox	20	2.0.0.0.00	
Avelox IV 400	20	Diclofenac sodium	
Azacitdine Dr Reddy's	11	,,	
Azacitidine		Dobutamine-hameln	
Azithromycin	10	Dobutamine hydrochloride	
В		Duolin	31
Baclofen		E	
Basiliximab	12	Elelyso	
Benzathine benzylpenicillin	10	Elocon	19
Beractant	31	Elocon Alcohol Free	19
Beta Cream	27	Eltrombopag	
Betamethasone dipropionate with calcipotriol	9	Enalapril maleate with hydrochlorothiazide	25
Betamethasone valerate	27	Endoxan	30
Beta Ointment	27	Entecavir	28
Beta Scalp	27	Entecavir Sandoz	28
Betnovate	9	Enteral feed 1.5 kcal/ml	23
Bezafibrate		Entresto 24/26	
Bezalip		Entresto 49/51	
Bezalip Retard		Entresto 97/103	
Bicillin LA		Eplerenone	
Biodone		Eptifibatide	
Diodollo	20	_punbaddo	10

Index

Pharmaceuticals and brands

Esbriet		Isotane 20		27
Ethambutol hydrochloride	10	Isotretinoin	26,	27
Ethics Lisinopril	8	Isradipine		26
Ethosuximide	21	J		
Etidronate disodium	28	Jakavi		11
F		L		
Felo 5 ER	8	Letrole		22
Felo 10 ER	8	Letrozole		
Felodipine	8	Lidocaine-Claris		
Fentanyl21,		Lidocaine [lignocaine] hydrochloride	10.	21
Ferrograd		Lignocaine		
Ferrous sulphate		Linezolid		
Ferrum H		Lisinopril		
Fingolimod		Lithicarb FC		
Flixonase Hayfever & Allergy		Lithium carbonate		
Flucloxacillin		M	••••	
Flumazenil		Magnesium chloride		19
Fluorouracil		Medrol		
Fluorouracil Ebewe 21,		Megestrol acetate		
· · · · · · · · · · · · · · · · · · ·		ě		
Fluticasone propionate		Meloxicam		
Folic acid		Meropenem		
Fucithalmic		Meropenem Ranbaxy		
Fusidic acid	31	Metformin hydrochloride		0
G		Methadone hydrochloride		
Gabapentin		Methylprednisolone acetate		
Gacet		Methylprednisolone (as sodium succinate)		
Galvumet		Metoprolol IV Mylan		
Galvus		Metoprolol tartrate		
Gentamicin sulphate		Miacalcic		
Gilenya	11	Minidiab		6
Glibenclamide	24	Mirtazapine		29
Glipizide	6	Mometasone furoate		19
Glycerol	24	Morphine hydrochloride		10
Granisetron	11	Moxifloxacin		20
H		Myambutol		10
healthE Calamine Aqueous Cream BP	19	Mylanta		
healthE Fatty Cream		Mylanta Double Strength		24
Heparin sodium	18	N		
Humira	22	Nadolol		26
HumiraPen	22	Naprosyn SR 750		28
I		Naprosyn SR 1000		
Imiglucerase	24	Naproxen		
Inspra		Neurontin	,	
Integrilin		Nifedipine		
Iron polymaltose		Nintedanib		
Isoniazid		Noflam 250		
Isoprenaline [isoproterenol]		Noflam 500		
Isoproterenol	18	Nupentin		
Isoptin		0	••••	۷۲
Isosource Standard RTH		Ofev		16
Isotane 10		Oil in water emulsion		
ISUIAITE TU	41	OII III WALEI EIIIUISIUII	•••••	č

Index

Pharmaceuticals and brands

Olanzapine	30	Somatropin
Omalizumab		Span-K
Omnitrope	27	Spiriva
Oratane		Spiriva Respimat.
Orion Temozolomide	21	SteroClear
Oxytocin		Survanta
Oxytocin BNM		Syntometrine
Oxytocin with ergometrine maleate	27	<u>T</u>
P		Tacrolimus
Pacifen	28	Tacrolimus Sando
Paracetamol	21	Taliglucerase alfa
Pedialyte Bubblegum	18	Temozolomide
Pharmacy Health SLS-free	27	Testosterone unde
Phenobarbitone	30	Thiamine hydroch
	26	Tiotropium bromio
Pioglitazone	24	TMP
Pirfenidone	17	Trandolapril
Potassium chloride	25	Tranexamic acid
Potassium citrate	27	Tranexamic-AFT
Promethazine theoclate	21	Trimethoprim
Propranolol	26	U
Prostin VR	8	Ursodeoxycholic a
Q		Ursosan
Quinapril	18	V
Quinapril with hydrochlorothiazide	8	Vedafil
R		Ventolin
RA-Morph	10	Verapamil hydrocl
Revolade		Vesicare
Ritonavir	21	Vexazone
Rivaroxaban 18,	25	Vfend
		Vildagliptin
S		Vildagliptin with m
Sacubitril with valsartan	8	Vitadol C
Salbutamol	-	Vitamin A with vita
	31	Voriconazole
Secukinumab	14	X
	19	Xarelto
	24	Xolair
	24	XP Maxamaid
	12	7
Siterone		Zarontin
Sodium acid phosphate	25	Ziprasidone
Sodium dihydrogen phosphate	23	Zithromax
	25	
		Zopiclone
,	31	Zopiclone Actavis
Solifenacin Mylan		Zusdone
Solifenacin succinate		Zyprexa Relprevv.
Solu-Medrol		Zyvox
Solu-Medrol Act-O-Vial	10	

	27
pan-K	25
piriva	16
piriva Respimat	16
teroClear	31
urvanta	31
yntometrine	27
acrolimus	12
acrolimus Sandoz	12
aliglucerase alfa	24
emozolomide	21
estosterone undecanoate	20
hiamine hydrochloride	18
iotropium bromide	16
MP	28
	25
ranexamic acid	25
ranexamic-AFT	25
	28
rimethoprim	20
rsodeoxycholic acid	0
	6
rsosan	6
edafil	19
entolin	23
erapamil hydrochloride18,	
esicare	
exazone	24
	10
ildagliptin	6
ildagliptin with metformin hydrochloride	6
itadol C	6
itamin A with vitamins D and C	6
oriconazole	10
, ,	
arelto	25
olair	
	17
arontin	
	21
	21 30
iprasidone	30
iprasidoneithromax	30 10
iprasidoneithromaxopiclone	30 10 11
iprasidonetirbromaxopicloneopiclone Actavis	30 10 11 11
iprasidone	30 10 11 11 30
iprasidonetirbromaxopicloneopiclone Actavis	30 10 11 11 30 30

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