

Drugs and guidelines update for GPs



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Introducing AusDoc's *Drugs and guidelines update for GPs* – your companion for navigating new and evolving treatment options. This concise reference is designed to help you keep abreast of recent TGA approvals, the latest PBS changes, emerging drug shortages, adverse events, safety alerts, and updates to treatment guidelines.

Noteworthy updates include the PBS-listing of inclisiran, an injectable lipid-lowering therapy catering for select patients with hypercholesterolaemia, alongside the TGA's approval of a second RSV vaccine for adults, and cloacasterone, a topical androgen receptor inhibitor for acne in those aged 12 and older.

In the evolving healthcare landscape, this resource serves as a guide, helping you to stay informed and equipped to provide the best care to your patients.

New TGA drug approvals	3
PBS updates	3
Current medicine shortages	6
Anticipated medicine shortages	7
Adverse events and safety alerts	7
Updated treatment guidelines	8

SOURCES: [TGA – Prescription medicines registrations](#) (16/04/24), [PBS summary of changes – 1 April 2024](#) (16/04/24), [TGA – medicine shortage reports database](#) (18/04/24), [TGA – System for Australian recall actions \(SARA\)](#) (18/04/24), [TGA – News and community](#) (18/04/24), [Department of Health and Aged Care](#) (18/04/24), [PBS Latest News](#) (18/04/24). All dates refer to the date of access.

NEW TGA DRUG APPROVALS
as of 1 April 2024

DRUG	FORM	INDICATION	DATE ON AUSTRALIAN REGISTER OF THERAPEUTIC GOODS
ANTI-INFECTIVES FOR SYSTEMIC USE			
Recombinant RSV pre-fusion F protein (ABRYSVO)	Vaccine	Immunisation of pregnant women or people aged 60 and older for prevention of RSV	20 MAR 2024
DERMATOLOGICAL			
Clascoterone (WINLEVI)	Cream	For the topical treatment of acne vulgaris in patients aged 12 and older	08 MAR 2024

DRUG	STRENGTH AND FORM	USE	PBS CODE(S)	UPDATE
ALIMENTARY TRACT AND METABOLISM				
Empagliflozin (JARDIANCE)	10mg tablet	Diabetes	14092Q	Addition of item
Tropisetron (TROPISERON-AFT)	5mg injection	Antiemetic	2746M	Deletion of item
ANTI-INFECTIVES FOR SYSTEMIC USE				
Azithromycin (AZITHROMYCIN)	500mg tablet	Uncomplicated urethritis due to <i>Chlamydia trachomatis</i>	8200N	Addition of Vitaris generic
		Trachoma	8336R	
Cefaclor (CEFACLOR)	Powder for oral liquid 125mg/5mL, 100 mL	Beta-lactam antibacterial	2460L	Addition of Sun Pharma generic
	Powder for oral liquid 250mg/5mL, 75 mL		2461M	
Tenofovir disoproxil fumarate + emtricitabine	300/200mg tablet	Pre-exposure prophylaxis against HIV infection	11276L	Addition of ARx generic

Continued next page

PBS UPDATES
as of 1 April 2024

PBS UPDATES
as of 1 April 2024

DRUG	STRENGTH AND FORM	USE	PBS CODE(S)	UPDATE
CARDIOVASCULAR SYSTEM				
Inclisiran (LEQVIO)	284mg injection	Lipid modifying agent (initial)	14101E	Addition of item
		Lipid modifying agent (continuing)	14087K	Addition of item
Irbesartan (IRBESARTAN)	75mg 2 x 30 tablets 1 x 30 tablets	Angiotensin II Receptor Blockers	13435D 8246B	Addition of Blooms The Chemist generic
	150mg 2 x 30 tablets 1 x 30 tablets		13380F 8247C	
	300mg 2 x 30 tablets 1 x 30 tablets		13564X 8248D	
MUSCULOSKELETAL SYSTEM				
Diclofenac sodium (FENAC EC)	25mg enteric tablet	NSAID	1299J	Deletion of Fenac and addition of Fenac EC brand
	50mg enteric tablet		1300K	
NERVOUS SYSTEM				
Ethosuximide (ETHOSUXIMIDE)	250mg capsule	Antiepileptic	13127X	Addition of item
Morphine sulfate pentahydrate modified release granules (MS CONTIN suspension)	20mg, 30mg, 60mg, 100mg, 200mg	Analgesic	Multiple codes	Deletion of item
Olanzapine (OLANZAPINE)	7.5mg tablet	Antipsychotic	8186W	Addition of Apotex generic
Paracetamol (PARAPANE OSTEO)	665mg modified release tablet	Analgesic	10797G	Addition of brand
Quetiapine (QUETIAPINE)	25mg tablet	Antipsychotic	8456C	Addition of APX brand
	200mg tablet		8458E	
	300mg tablet		8580N	

PBS UPDATES
as of 1 April 2024

DRUG	STRENGTH AND FORM	USE	PBS CODE(S)	UPDATE
RESPIRATORY SYSTEM				
Fluticasone propionate + salmeterol (SALFUMIX)	250/50µg inhaler	Obstructive airway diseases, asthma	8431R	Addition of brand; and alteration to restriction related to prior corticosteroids
	500/50µg inhaler		8432T	
VARIOUS				
Methotrexate (TREXJECT)	7.5mg injection	Severe active juvenile idiopathic arthritis	14091P	Addition of item
	10mg injection		14089M	
	15mg injection		14102F	
	20mg injection		14097Y	
	25mg injection		14103G	
Methylprednisolone (METHYLPRED)	40mg injection	Systemic corticosteroid	5263B	Deletion of item Modified release injection remains listed
Methylprednisolone (SOLUMEDROL)	40mg injection	Systemic corticosteroid	11739W	Alteration to note stating that these two items are equivalent for the purposes of substitution
Methylprednisolone (SOLUMEDRONE)			13736Y	

CURRENT MEDICINE SHORTAGES

as of 18 April 2024

DRUG	OUT OF STOCK UNTIL	SUBSTITUTE OR MANAGEMENT ACTION
ALIMENTARY TRACT AND METABOLISM		
CARBOSORB activated charcoal and sorbitol	17 JUN 2024	
ANTI-INFECTIVES FOR SYSTEMIC USE		
BICILLIN L-A (benzathine benzylpenicillin tetrahydrate) 1,200,000 units / 2.3mL suspension for injection pre-filled syringe with needle		Emergency supply only Section 19A ¹
RIMYCIN 150 (rifampicin) 150mg capsule	30 MAY 2024	Section 19A ²
RIMYCIN 300 (rifampicin) 300mg capsule	21 JUN 2024	Limited availability Section 19A ²
Vaxchora (Vibrio cholerae bacteria cells) suspension, powder, sachet	30 APR 2024 (No further updates)	Limited availability Section 19A ³
CARDIOVASCULAR SYSTEM		
ACCURETIC 10/12.5 tablet (hydrochlorothiazide quinapril hydrochloride)	31 DEC 2024	
ACCURETIC 20/12.5 tablet (hydrochlorothiazide quinapril hydrochloride)	31 DEC 2024	
XYLOCAINE 0.5% with Adrenaline 20mL vial	31 DEC 2024	Other strengths available
DERMATOLOGICAL		
FLAMAZINE (silver sulfadiazine 1%)	15 APR 2024 (No further updates)	
NERVOUS SYSTEM		
TOFRANIL (imipramine) 25mg tablet	31 DEC 2024	Section 19A ³
ZARONTIN (ethosuximide) 250mg capsule	31 JUL 2024	Section 19A ³
VARIOUS		
MAREVAN (warfarin) 5mg tablet	17 MAY 2024	The sponsor is closely controlling the supply
SOLU-CORTEF ACT-O-VIAL (hydrocortisone) 250mg powder for injection and diluent dual-chamber vial	30 SEP 2024	
SYNACTHEN DEPOT (tetracosactide [tetracosactrin] zinc complex) 1mg/1mL ampoule	30 NOV 2026	

1. An unregistered product has been approved for supply under Section 19A. Contact Orspec Pharma Pty Ltd on (02) 4339 4239. A TGA web alert is available [here](#).
2. An unregistered product has been approved for supply under Section 19A. Contact Sanofi-Aventis Australia Pty Ltd on 1800 818 806.
3. An unregistered product has been approved for supply under Section 19A. [Click here](#) and search for the active ingredient.

CURRENT MEDICINE SHORTAGES

as of 1 April 2024

ANTICIPATED MEDICINE SHORTAGES

OZEMPIC (semaglutide)

There is an ongoing shortage of OZEMPIC (semaglutide) with limited availability until 31 December 2024. A TGA statement is available [here](#). Unregistered products have been approved for supply under Section 19A. The following approval holders can be contacted for details on supply:

- Medsurge Pty Ltd: 1300 788 261 • sales@medsurge.com.au
- Pro Pharmaceuticals Group: 1300 077 674 • info@propg.com.au

DRUG	SUPPLY IMPACT DATES
MAREVAN (warfarin sodium) 5mg tablet	From 23 April 2024 to 17 May 2024
ISONIAZID (isoniazid) 100mg tablet	From 07 Jun 2024 to 09 Aug 2024

PRODUCT NAME	DESCRIPTION	RECALL REASON	ACTION LEVEL	DATE
Clear the Skin Formula a.k.a. Liang Xue Xiao Feng San	All Batches Expiry date: 16/11/2024	Missing pregnancy warning for the ingredient <i>Artemisia frigida</i> .	Consumer level recall	18 MAR 2024
K-Citra 10 Tablets Potassium Citrate 1080mg	Batch number: 42301133-B, 42204121-B	Labelling error regarding the content of equivalent Potassium and equivalent Citrate.	Retail level recall	27 MAR 2024
Cellife AMPK Fatburst	Batch number: 07258 Expiry date: 12/2026	Missing mollusc product warning for the ingredient oyster shell.	Retail level recall	8 APR 2024

Compounded semaglutide

The TGA issued a [media release](#) on 5 April 2024 related to an ongoing investigation into the alleged unlawful manufacture, supply and export of therapeutic goods. The alert noted that several patients have experienced adverse events and additional medical issues caused after the substance had been posted to them from a source purporting to be a pharmacy.

A [safety alert](#) for substandard semaglutide vials was also issued on 28 March 2024.

Information about counterfeit medicines and patient safety is available [here](#).

Diabetes Australia has a [related article](#).

TGA Database of Adverse Events

Search the [Database of Adverse Event Notifications \(DAEN\) – medicines](#).

ADVERSE EVENTS AND SAFETY ALERTS

as of 18 April 2024

Cardiac Society of Australia and New Zealand

Guidance on myocarditis and pericarditis after mRNA COVID-19 vaccines. [Click here](#).

ATAGI clinical advice March 2024

RSV vaccine — AREXY RSV is a single dose vaccine currently available on the private market in Australia for adults aged ≥60 to prevent illness and severe complications associated with RSV infection. It is not currently funded under the National Immunisation Program. Refer to [ATAGI's clinical advice statement](#) for full details.

PBS news

The agenda for the July 2024 PBAC meeting is [now available](#). Comments are welcome from patients, carers, members of the public, health professionals and consumer interest groups. Information about the PBAC process and how to provide input can be found on the [Office of Health Technology Assessment \(OHTA\) Consultation Hub](#).

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