Anti-Seizure Medications in Australia

Prescriber's Identification Guide

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FOREWORD

The idea of providing an illustrated list of anti-seizure medications (ASM) available in Australia started a number of years ago after countless clinical consultations where patients did not know exactly what they were taking. Often we were told something like, "I'm taking two little red pills... and the purple ones, of course."

After frustrating and time-consuming searches through MIMS and various websites, as well as being put endlessly on hold by GP practices or pharmacies, we created a list of ASMs and their respective PBS codes. This was helpful but obviously didn't solve the issue of patient identification of what ASMs they were taking.

When we found a UK booklet of ASMs showing pictures of the medication box and tablet/capsules, we wondered if we could create a similar booklet for Australian practitioners that included relevant PBS information. With the support of Eisai Australia, we have managed to do just that. We trust you will find it useful.

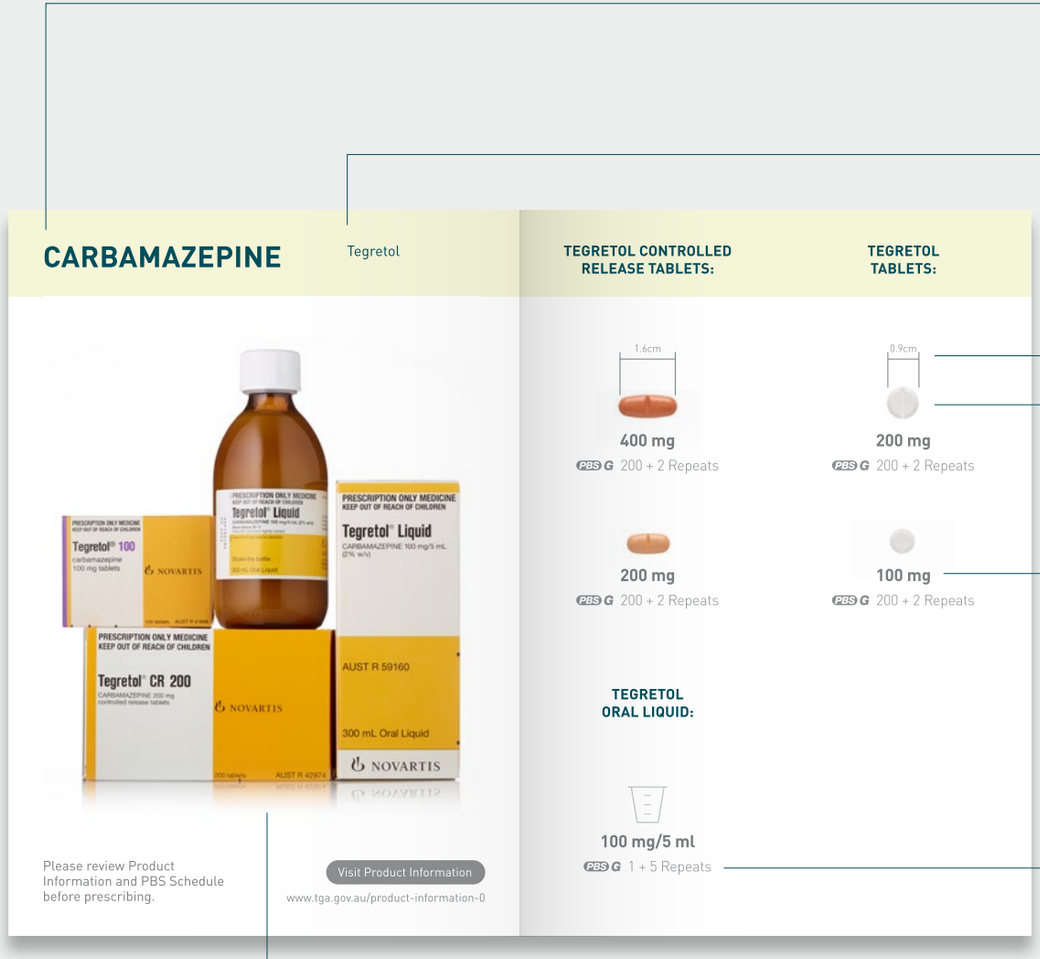
Judy Lee
Epilepsy Clinical Nurse
Western Australia Adult Epilepsy Service

This guide is intended for use by Australian Healthcare Professionals only.

For each ASM, photographs of the main brand's packaging and presentations are included, along with information about their availability. The URL is also provided for the TGA Product Information search website. This is the most appropriate resource as it ensures the prescriber is accessing the most up-to-date version of the Product Information for any given ASM. A listing of all PBS Streamlined Authority Codes for the applicable epilepsy medications is also included at the back of this guide.

Every effort has been made to ensure that, at the time of printing, the information in this booklet is accurate and current. However, PBS codes can change over time and new ASMs will become available. While the intention is to update this booklet on a regular basis (including an online format), this booklet is not in any way intended to replace MIMs or the PBS schedule for doctors when prescribing ASMs.

*Injectable formulations, with the exception of midazolam, and IV formulations are not included in this booklet.



Drug name

Known brand name(s) – Note: generic brands that use the drug name are not listed, eg. 'Carbamazepine Sandoz'

Length/diameter of largest tablet/capsule (and all tablets/capsules shown as close as possible to actual size)

Images of all tablets/capsules of main brand

Dosage strength of each tablet/capsule

PBS availability of each presentation – Note: 'PBS G' means General Schedule; 'PBS A' means Authority Required

Images of lowest doses of available presentations of main brand, eg. capsules and oral liquid

ACETAZOLAMIDE

Diamox

DIAMOX TABLETS:

250 mg

PBS G 100 + 3 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

BRIVARACETAM

Briviact

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

BRIVIACT TABLETS:

100 mg

PBS A 56 + 5 Repeats

75 mg

PBS A 56 + 5 Repeats

50 mg

PBS A 56 + 5 Repeats

25 mg

PBS A 56 + 5 Repeats

BRIVIACT ORAL SOLUTION:

10 mg/mL

PBS A 1 + 5 Repeats

CANNABIDIOL

Epidyolex

EPIDYOLEX ORAL LIQUID:

100 mg/1 mL

PBS A 1 + 5 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

CARBAMAZEPINE

Tegretol

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

TEGRETOL CONTROLLED RELEASE TABLETS:

400 mg

PBS G 200 + 2 Repeats

200 mg

PBS G 200 + 2 Repeats

TEGRETOL ORAL LIQUID:

100 mg/5 ml

PBS G 1 + 5 Repeats

TEGRETOL TABLETS:

200 mg

PBS G 200 + 2 Repeats

100 mg

PBS G 200 + 2 Repeats

CLOBAZAM

Frisium, Clobium

FRISIUM TABLETS:

10 mg

Not PBS listed

Visit Product Information

Please review Product Information before prescribing.

CLONAZEPAM

Paxam, Rivotril

PAXAM TABLETS:

2 mg

PBS A 200 + 2 Repeats

0.5 mg

PBS A 200 + 2 Repeats

PAXAM ORAL LIQUID:

2.5 mg/mL

PBS A 2 + 0 Repeats

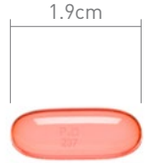
Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

ETHOSUXIMIDE

Zarontin

ZARONTIN CAPSULES:



250 mg

PBS G 200 + 2 Repeats

ZARONTIN ORAL LIQUID:

250 mg/5 mL

PBS G 1 + 5 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

GABAPENTIN

Neurontin, Gabacor, Gabaran, Gantin, Gapentin, Nupentin

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

NEURONTIN TABLETS:

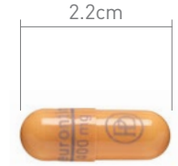
800 mg

PBS A 100 + 5 Repeats

600 mg

PBS A 100 + 5 Repeats

NEURONTIN CAPSULES:



400 mg

PBS A 100 + 5 Repeats

300 mg

PBS A 100 + 5 Repeats

100 mg

PBS A 100 + 5 Repeats

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

LACOSAMIDE

Vimpat

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

VIMPAT TABLETS:

200 mg

PBS A 56 + 5 Repeats (maintenance)

150 mg

PBS A 14 + 1 Repeat (initial); 56 + 5 Repeats (maintenance)

100 mg

PBS A 14 + 1 Repeat (initial); 56 + 5 Repeats (maintenance)

50 mg

PBS A 14 + 1 Repeat (initial); 56 + 5 Repeats (maintenance)

VIMPAT ORAL SOLUTION:

10 mg/mL

PBS A 6 + 5 Repeats

LAMOTRIGINE

Lamictal, Lamidus, Lamitan, Lamotrust, Logem

LAMICTAL TABLETS:

200 mg

PBS A 56 + 5 Repeats

100 mg

PBS A 56 + 5 Repeats

50 mg

PBS A 56 + 5 Repeats

25 mg

PBS A 56 + 5 Repeats

5 mg

PBS A 56 + 5 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

LEVETIRACETAM

Keppra, Kerron, Kevtam,
Levecetam, Levactam, Levi

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

KEPPRA TABLETS:

1000 mg

PBS A 60 + 5 Repeats

500 mg

PBS A 60 + 5 Repeats

250 mg

PBS A 60 + 5 Repeats

KEPPRA ORAL LIQUID:

100 mg/mL

PBS A 1 + 5 Repeats

MIDAZOLAM

Hypnovel

MIDAZOLAM AMPOULES FOR INJECTION:

5 mg/mL

PBS G 1 + 0 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

OXCARBAZEPINE

Trileptal

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

TRILEPTAL TABLETS:

600 mg

PBS A 100 + 5 Repeats

300 mg

PBS A 100 + 5 Repeats

150 mg

PBS A 100 + 5 Repeats

TRILEPTAL ORAL LIQUID:

60 mg/mL

PBS A 2 + 5 Repeats

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PERAMPANEL

Fycompa

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

FYCOMPA TABLETS:

0.8cm

12 mg
PBS A 28 + 5 Repeats

4 mg
PBS A 28 + 5 Repeats

10 mg
PBS A 28 + 5 Repeats

2 mg
PBS A 14 + 1 Repeats

8 mg
PBS A 28 + 5 Repeats

FYCOMPA ORAL SUSPENSION:

6 mg
PBS A 28 + 5 Repeats

2 mg/4 mL
Not PBS listed

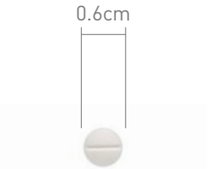
Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PHENOBARBITAL
(phenobarbitone)

Phenobarb

PHENOBARB TABLETS:



30 mg

PBS G 200 + 4 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PHENYTOIN

Dilantin

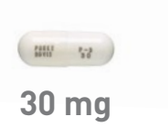
Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

DILANTIN CAPSULES:

100 mg

PBS G 200 + 2 Repeats



30 mg

PBS G 200 + 2 Repeats

DILANTIN INFATABS (CHEWABLE TABLETS):

50 mg

PBS G 200 + 2 Repeats

DILANTIN ORAL SUSPENSION:

30 mg/5 mL

PBS G 1 + 3 Repeats

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PREGABALIN

Lyrica, Lypralin,
Lyzalon, Neuroccord

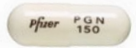
Visit Product Information

Please review Product Information before prescribing.

LYRICA CAPSULES:

300 mg

Not PBS listed



150 mg

Not PBS listed

75 mg

Not PBS listed

25 mg

Not PBS listed

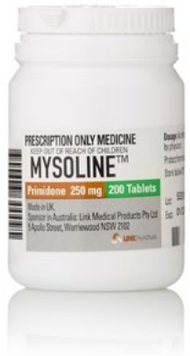
Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PRIMIDONE

Mysoline,
Apo-Primidone

MYSOLINE TABLETS:



250 mg

PBS G 200 + 2 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

RUFINAMIDE

Inovelon

INOVELON TABLETS:

400 mg

Not PBS Listed

200 mg

Not PBS Listed

Visit Product Information

Please review Product Information before prescribing.

STIRIPENTOL

Diacomit

DIACOMIT CAPSULES:

500 mg

PBS A 120 + 3 Repeats

250 mg

PBS A 120 + 3 Repeats

DIACOMIT SACHETS:

500 mg

PBS A 120 + 3 Repeats

250 mg

PBS A 120 + 3 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

SULTHIAME

Ospolot

OSPOLOT TABLETS:

200 mg

PBS G 200 + 2 Repeats

50 mg

PBS G 200 + 2 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

TIAGABINE

Gabitril

GABITRIL TABLETS:

15 mg

PBS A 100 + 5 Repeats

10 mg

PBS A 100 + 5 Repeats

5 mg

PBS A 100 + 5 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

TOPIRAMATE

Topamax, Epiramax, Tamate

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

TOPAMAX TABLETS:

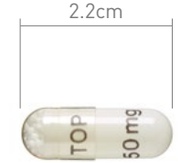
200 mg
PBS A 60 + 5 Repeats

100 mg
PBS A 60 + 5 Repeats

50 mg
PBS A 60 + 5 Repeats

25 mg
PBS A 60 + 5 Repeats

TOPAMAX SPRINKLE CAPSULES:



50 mg
PBS A 60 + 5 Repeats

25 mg
PBS A 60 + 5 Repeats

15 mg
PBS A 60 + 5 Repeats

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

VALPROATE

Epilim, Valprease, Valpro

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

EPILIM ENTERIC TABLETS:

500 mg

PBS G 200 + 2 Repeats

200 mg

PBS G 200 + 2 Repeats

EPILIM TABLETS:

100 mg

PBS G 200 + 2 Repeats

EPILIM ORAL LIQUID:

200 mg/5 mL

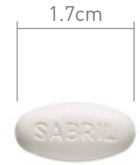
PBS G 2 + 2 Repeats

VIGABATRIN

Sabril

SABRIL TABLETS:

SABRIL SACHETS:



500 mg

PBS A 100 + 5 Repeats

500 mg

PBS A 60 + 5 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

ZONISAMIDE

Zonegran

ZONEGRAN CAPSULES:

100 mg

PBS A 112 + 5 Repeats

50 mg

PBS A 56 + 5 Repeats

25 mg

PBS A 56 + 5 Repeats

Visit Product Information

Please review Product Information and PBS Schedule before prescribing.

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PBS AUTHORITY CODES

Medication	Formulation (PBS Quantity)	PBS Authority Code			
		Partial-Onset Seizures		Generalised Epilepsy	
		Initial	Continuing	Initial	Continuing
Brivaracetam	25 mg tablet (56 + 5) 50 mg tablet (56 + 5) 75 mg tablet (56 + 5) 100 mg tablet (56 + 5)	10210	10208	–	–
	10 mg/mL oral liquid (1 + 5)	10251	10330	–	–
Cannabidiol	100 mg/mL oral solution (1+ 5)	Phone for Authority approval			
Clonazepam	0.5 mg tablet (200 + 2) 2 mg tablet (100 + 2)	Phone for Authority approval			
	2.5 mg/mL oral liquid (2 + 0)	Phone for Authority approval			
Gabapentin	100 mg capsules (100 + 5) 300 mg capsules (100 + 5) 400 mg capsules (100 + 5)	4928		–	
	600 mg tablets (100 + 5) 800 mg tablets (100 + 5)	4928		–	
Lacosamide	50 mg tablets (14 + 1) 50 mg tablets (56 + 5) 100 mg tablets (14 + 1) 100 mg tablets (56 + 5) 150 mg tablets (14 + 1) 150 mg tablets (56 + 5) 200 mg tablets (56 + 5)	8813 – 8813 8770 8813 8770 8770	– 8815 – 8815 – 8815 8815	– 12092 12225 12092 12225 12092 12092	
	10 mg/mL oral liquid (6 + 5)	8770	8815	12092	

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PBS AUTHORITY CODES

Medication	Formulation (PBS Quantity)	PBS Authority Code			
		Partial-Onset Seizures		Generalised Epilepsy	
		Initial	Continuing	Initial	Continuing
Lamotrigine	5 mg tablets (56 + 5) 25 mg tablets (56 + 5) 50 mg tablets (56 + 5) 100 mg tablets (56 + 5) 200 mg tablets (56 + 5)	11081			
Levetiracetam	250 mg tablets (60 + 5) 500 mg tablets (60 + 5) 1,000 mg tablets (60 + 5)	11116		–	
	100 mg/mL oral liquid (1 + 5)	11077		–	
Oxcarbazepine	150 mg tablet (100 + 5) 300 mg tablet (100 + 5) 600 mg tablet (100 + 5)	5183			
	60 mg/mL oral liquid (2 + 5)	5183			
Perampanel	2 mg tablet (14 + 1) 4 mg tablet (28 + 5) 6 mg tablet (28 + 5) 8 mg tablet (28 + 5) 10 mg tablet (28 + 5) 12 mg tablet (28 + 5)	4656 – – – – –	– 4658 4658 4658 4658 4658	7815 – – – – –	– 7789 7789 7789 7789 7789
Stiripentol	250 mg capsule (120 + 3) 500 mg capsule (120 + 3)	–		11642 (SAS)	
	250 mg powder (120 + 3) 500 mg powder (120 + 3)	–		11642 (SAS)	
Tiagabine	5 mg tablet (100 + 5) 10 mg tablet (100 + 5) 15 mg tablet (100 + 5)	4928	–		

Acetazolamide
Brivaracetam
Cannabidiol
Carbamazepine
Clobazam
Clonazepam
Ethosuximide
Gabapentin
Lacosamide
Lamotrigine
Levetiracetam
Midazolam
Oxcarbazepine
Perampanel
Phenobarbital
Phenytoin
Pregabalin
Primidone
Rufinamide
Stiripentol
Sulthiame
Tiagabine
Topiramate
Valproate
Vigabatrin
Zonisamide

PBS Authority Codes

PBS AUTHORITY CODES

Medication	Formulation (PBS Quantity)	PBS Authority Code			
		Partial-Onset Seizures		Generalised Epilepsy	
		Initial	Continuing	Initial	Continuing
Topiramate	25 mg tablet (60 + 5) 50 mg tablet (60 + 5) 100 mg tablet (60 + 5) 200 mg tablet (60 + 5)	5516			
	15 mg capsule (60 + 5) 25 mg capsule (60 + 5) 50 mg capsule (60 + 5)	5173			
Vigabatrin	500 mg tablet (100 + 5)	4929			
	500 mg powder (60 + 5)	4929			
Zonisamide	25 mg capsule (56 + 5) 50 mg capsule (56 + 5) 100 mg capsule (112 + 5)	4928		–	

For up-to-date PBS information:

Visit PBS Website

FYCOMPA PRESCRIBING INFORMATION

PBS Information: Authority Required (Streamlined) for intractable partial epileptic seizures and idiopathic generalised epilepsy with primary generalised tonic-clonic seizures. Refer to PBS Schedule for full Authority information.

Please review the Product Information before prescribing, available from www.eisai.com.au/PI

▼ This medicinal product is subject to additional monitoring in Australia due to approval of an extension of indications. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems

Minimum Product Information: Fycompa® (perampanel). **INDICATIONS**: Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients from 4 years of age with epilepsy. Adjunctive treatment of primary generalised tonic-clonic seizures in patients from 7 years of age with idiopathic generalised epilepsy. **CONTRAINDICATIONS**: Hypersensitivity to perampanel or any of the excipients. **PRECAUTIONS**: Not recommended in children <4 years; use in elderly (use with caution); suicidal ideation and behaviour (monitor for emergence or worsening depression, suicidal thoughts or behaviour and unusual changes in mood or behaviour); Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)/Multiorgan hypersensitivity; nervous system disorders (dizziness, gait disturbance, somnolence and fatigue); falls (caution with elderly); recommend gradual discontinuation; serious psychiatric and behavioural reactions (monitor for changes in mood, behaviour or personality, particularly during titration and higher doses. Reduce dose if symptoms occur, discontinue if severe); abuse potential (caution with history of substance abuse); monotherapy not recommended; galactose intolerance (do not take with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption); sorbitol (do not take oral suspension with fructose intolerance, use caution when combining oral suspension with other antiepileptic medications containing sorbitol); pregnancy (category B3), not recommended; unknown if excreted in human milk (assess risk benefit); hepatotoxicity (mainly hepatic enzyme increase). **INTERACTIONS**: Oral contraceptives (consider decreased efficacy of progestative containing OCs for women needing 12 mg/day and additional non-hormonal form of contraception); other antiepileptic drugs (AEDs; enzyme inducers carbamazepine, phenytoin, and oxcarbazepine) increase perampanel clearance and decrease concentration, dose to clinical effect regardless of other AEDs; dose of perampanel may need to be adjusted according to CYP450 inhibitor and inducer coadministration; possible additive effects with CNS depressants (alcohol). **ADVERSE REACTIONS**: (≥12 years): dizziness, somnolence, fatigue, irritability, falls, nausea, ataxia, balance disorder, gait disturbance, back pain, vertigo, headache and weight gain. Aggression was observed more frequently in adolescents than adults. Children 4 to <12 years: somnolence, nasopharyngitis, dizziness, irritability, pyrexia, vomiting (somnolence, irritability, aggression, and agitation were observed more frequently than in adolescents and adults). **DOSAGE AND ADMINISTRATION**: Film-coated tablets: 2 mg, 4 mg, 6 mg, 8 mg, 10 mg and 12 mg. Oral suspension 2 mg/4 mL. Adults and adolescents ≥12 years, and children <12 years and ≥30 kg: Initiate at 2 mg and titrate weekly or longer according to individual response to maintenance dose of 4 mg/day to 12 mg/day. Children <12 years, and ≥20 kg and <30 kg: Initiate at 1 mg and titrate weekly or longer according to individual response to maintenance dose of 4 mg/day to 8 mg/day. Children <12 years, and <20 kg: Initiate at 1 mg and titrate weekly or longer according to individual response to maintenance dose of 2 mg/day to 6 mg/day. Take orally once daily at bedtime, with or without food, swallowed whole with a glass of water (tablets) or via oral syringe (suspension). Not recommended in moderate or severe renal impairment or patients undergoing haemodialysis. Caution in mild to moderate hepatic impairment, do not exceed 8 mg (no dosing recommendation in children <12 years). Not recommended in severe hepatic impairment. Date of most recent amendment: March 2021.

INOVELON PRESCRIBING INFORMATION

PBS Information: This product is not listed on the PBS.

Please review the Product Information before prescribing, available from www.eisai.com.au/PI

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems

Minimum Product Information: Inovelon® (rufinamide). **INDICATION**: Adjunctive treatment of seizures associated with Lennox Gastaut syndrome in patients 4 years of age and older. **CONTRAINDICATIONS**: Hypersensitivity to rufinamide, triazole derivatives or any of the excipients. **PRECAUTIONS**: Status epilepticus (assess benefit risk ratio if new seizure types or increased frequency of status epilepticus occurs); recommend gradual withdrawal; central nervous system reactions (dizziness, somnolence, ataxia and gait disturbances; can increase accidental falls); hypersensitivity reactions including DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms) and Stevens-Johnson syndrome; QT shortening (use clinical judgement in patients with existing QT shortening); women of childbearing potential must use contraceptive measures; lactose (do not take with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption); suicidal ideation (monitor for signs of suicidal ideation and behaviours); pregnancy (category B3), not recommended; unknown if excreted in human milk (assess risk benefit). **INTERACTIONS**: Valproate (consider dose reduction in patients receiving valproate and dose adjustment for valproate addition or withdrawal); oral contraceptives (use additional non-hormonal contraceptive method);carefully monitor patients treated with CYP3A4 substrates or substances with a narrow therapeutic window (warfarin, digoxin) for two weeks at the start of, or after the end of treatment with Inovelon, or after any marked change in dose, and consider dose adjustment of the concomitant medicine. **ADVERSE REACTIONS**: Somnolence, headache, dizziness, nausea, vomiting, fatigue, pneumonia, influenza, nasopharyngitis, ear infection, sinusitis, rhinitis, anorexia, eating disorder, decreased appetite, anxiety, insomnia, status epilepticus, convulsion, coordination abnormal, nystagmus, psychomotor hyperactivity, tremor, diplopia, vision blurred, vertigo, epistaxis, abdominal pain upper, constipation, dyspepsia, diarrhoea, rash, acne, back pain, oligomenorrhoea, gait disturbance, weight decrease, head injury and contusion. **DOSAGE AND ADMINISTRATION**: Film-coated tablets: 200 mg, 400 mg. Take twice-daily in the morning and evening in two equally divided doses with food. Can be crushed and administered in half a glass of water. Patients less than 30 kg: Initiate at a total daily dose of 200 mg. According to response and tolerability, the total daily dose can be increased by 200 mg/day as frequently as every third day up to a maximum recommended dose of 1000 mg/day in patients not receiving valproate, or 600 mg/day in patients receiving valproate. Patients 30 kg or over: Initiate at a total daily dose of 400 mg. According to response and tolerability, the total daily dose can be increased by 400 mg/day as frequently as every other day. The maximum recommended dose in patients not receiving valproate are 1800 mg/day (30–50 kg), 2400 mg/day (50.1–70 kg) and 3200 mg/day (≥70.1 kg); and in patients receiving valproate are 1200 mg/day (30–50 kg), 1600 mg/day (50.1–70 kg) and 2200 mg/day (≥70.1 kg). Careful dose titration in mild to moderate hepatic impairment, use in severe hepatic impairment not recommended. Date of most recent amendment: June 2018.

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To report an adverse event for any agent in this guide,
visit https://www.tga.gov.au/reporting-problems
For Fycompa and Inovelon, adverse events can
alternatively be reported directly to Eisai at Safety_Australia@eisai.net.

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