



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	81812	GABAPENTIN-GA gabapentin 400 mg capsule blister pack
ARTG entry for	Medicine Registered	
Sponsor	Medis Pharma Pty Ltd	
Postal Address	Locked Bag 2053, North Ryde, NSW, 1670 Australia	
ARTG Start Date	9/05/2002	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . GABAPENTIN-GA gabapentin 400 mg capsule blister pack

Product Type	Single Medicine Product	Effective Date	9/06/2010
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Gabapentin is indicated for the treatment of partial seizures, including secondarily generalised tonic-clonic seizures, initially as add-on therapy in adults and children age 3 years and above who have not achieved adequate control with standard anti-epileptic drugs. Gabapentin is indicated for the treatment of neuropathic pain.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
100 capsule	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Capsule
Route of Administration	Oral
Visual Identification	hard gelatin capsules with white opaque body and an orange opaque cap. "Apo 114" is imprinted on each capsule in black ink.

Active Ingredients

gabapentin	400 mg
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Other Ingredients (Excipients)

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butan-1-ol
croscarmellose sodium
ethanol
Gelatin
iron oxide black
iron oxide red
iron oxide yellow
isopropyl alcohol
magnesium stearate
potassium hydroxide
propylene glycol
purified talc
purified water
Shellac
strong ammonia solution
titanium dioxide

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