



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	58627	CILOPEN VK phenoxymethylpenicillin (as potassium) 250mg 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	21/02/1997	
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 . CILOPEN VK 250mg capsule blister pack

Product Type	Single Medicine Product	Effective Date	18/11/2008
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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

When oral therapy is required in the treatment of mild to moderately severe infections due to penicillin sensitive organisms. Therapy should be guided by bacteriological studies, including sensitivity tests, and by clinical response. For prophylactic use in recurrent streptococcal infections including the prevention of recurrence following rheumatic fever and/or Sydenham's chorea, and to prevent bacterial endocarditis in patients with rheumatic and/or congenital heart disease who are about to undergo dental or upper respiratory surgery or instrumentation. Note. Oral penicillin should not be used as adjunctive prophylaxis for genitourinary instrumentation or surgery, lower intestinal tract surgery, sigmoidoscopy or complications of childbirth.

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
25 capsules	(S4) Prescription Only Medicine
50 capsules	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Size 2 hard gelatin capsule, opaque white body and opaque yellow cap

Active Ingredients

phenoxymethylpenicillin potassium	279 mg
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Equivalent: phenoxymethylpenicillin

250 mg

Other Ingredients (Excipients)

Gelatin

magnesium stearate

quinoline yellow

titanium dioxide

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