



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	58628	CILOPEN VK phenoxymethylpenicillin (as potassium) 500mg capsule blister pack
<b>ARTG entry for</b>	Medicine Registered	
<b>Sponsor</b>	Medis Pharma Pty Ltd	
<b>Postal Address</b>	Locked Bag 2053, North Ryde, NSW, 1670 Australia	
<b>ARTG Start Date</b>	21/02/1997	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 500mg capsule blister pack**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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**

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	Size 0 hard gelatin capsule, opaque white body and opaque yellow cap.

**Active Ingredients**

phenoxymethylpenicillin potassium	559 mg
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Equivalent: phenoxymethylpenicillin

500 mg

**Other Ingredients (Excipients)**

**Gelatin**  
**magnesium stearate**  
**quinoline yellow**  
**titanium dioxide**

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