



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	75561	CEFKOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle
<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>	28/09/2000	
<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 . CEFKOR cefaclor 250mg/5mL (as monohydrate) powder for oral liquid bottle**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/03/2011
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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**

Other Shelf Life and Storage Conditions: 14 days and Store between 2-8 degrees C and Protect from Light. INDICATIONS: Infections due to susceptible microorganisms. Lower respiratory infections, including pneumonia, bronchitis and exacerbations of chronic bronchitis. Upper respiratory tract infections, including pharyngitis and tonsillitis and otitis media. Note: Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. Cefaclor appears to be as effective as phenoxymethylpenicillin in the eradication of Streptococci from the nasopharynx; however, substantial data establishing the efficacy of cefaclor in the subsequent prevention of rheumatic fever are not available at present. Skin and skin structure infections. Urinary tract infections, including pyelonephritis and cystitis. Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to cefaclor.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	18 Months	Store below 25 degrees Celsius	Not recorded	Protect from Light

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
75mL (Reconstituted)	(S4) Prescription Only Medicine

**Components**

**1 . Medicine Component**

<b>Dosage Form</b>	Oral Liquid, powder for
<b>Route of Administration</b>	Oral
<b>Visual Identification</b>	White to off-white granular powder forming a red suspension on reconstitution with water

**Active Ingredients**

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<b>cefaclor monohydrate</b>	<b>52.45 mg/mL</b>
Equivalent: cefaclor	50 mg/mL

**Other Ingredients (Excipients)**

allura red AC  
carmellose sodium  
citric acid  
colloidal anhydrous silica  
Flavour  
polysorbate 60  
simethicone  
sodium benzoate  
sodium citrate dihydrate  
sorbic acid  
sorbitan monostearate  
sucrose  
water for injections  
xanthan gum

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