



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	75560	CEF KOR cefaclor 125mg/5mL (as monohydrate) powder for oral liquid bottle
ARTG entry for	Medicine Registered	
Sponsor	Medis Pharma Pty Ltd	
Postal Address	Locked Bag 2053, North Ryde, NSW, 1670 Australia	
ARTG Start Date	28/09/2000	
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 . CEF KOR cefaclor 125mg/5mL (as monohydrate) powder for oral liquid bottle

Product Type	Single Medicine Product	Effective Date	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

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

Pack Size	Poison Schedule
100mL (reconstituted)	(S4) Prescription Only Medicine

Components

1 . Medicine Component

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

Active Ingredients

cefaclor monohydrate	26.23 mg/mL
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Equivalent: cefaclor

25 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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