



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	67946	CILEX cefalexin 500mg 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	16/04/1999	
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 . CILEX cefalexin 500mg capsule blister pack

Product Type	Single Medicine Product	Effective Date	2/02/2011
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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

Treatment of the following bacterial infections when caused by susceptible strains of the designated micro-organisms. Respiratory tract infections; Strep. pneumoniae and group A B-haemolytic streptococci. Although penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections (including the prophylaxis of rheumatic fever), cephalexin is generally effective in the eradication of streptococci from the nasopharynx. Substantial data establishing the efficacy of cephalexin in the subsequent prevention of rheumatic fever are not available at present. Bacterial sinusitis: Streptococci, Strep. pneumoniae and Staph. aureus (methicillin sensitive only). Otitis media: Strep. pneumoniae, staphylococci (methicillin sensitive only). Skin and skin structure infections: Staphylococci (methicillin sensitive only) and/or streptococci. Genitourinary tract infections, including acute prostatitis: E.coli, P.mirabilis, and Klebsiella sp. The effectiveness of cephalexin in the treatment of bacterial infections of the brain and spinal column has not been established and CILEX is not indicated in these conditions. Note. Appropriate culture and susceptibility tests should be initiated prior to and during therapy to determine susceptibility of the causative organism to CILEX. Renal function studies should be performed when indicated.

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	2 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light Protect from Moisture

Pack Size/Poison information

Pack Size	Poison Schedule
20 capsules	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	Dark green/light green, hard gelatin, self locked Size 0 capsule, imprinted with two parallel black lines on both the cap &

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body, containing white to off-white granular powder/pellet.

Active Ingredients

cefalexin monohydrate

Equivalent: cefalexin

500 mg

Other Ingredients (Excipients)

butan-1-ol

ethanol

Gelatin

iron oxide black

isopropyl alcohol

lactose monohydrate

magnesium stearate

patent blue V

potassium hydroxide

propylene glycol

purified water

quinoline yellow

Shellac

strong ammonia solution

titanium dioxide

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