



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	28637	CLOSINA cycloserine 250mg capsule bottle
ARTG entry for	Medicine Registered	
Sponsor	Aspen Pharmacare Australia Pty Ltd	
Postal Address	34-36 Chandos Street, ST LEONARDS, NSW, 2065 Australia	
ARTG Start Date	4/11/1991	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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 . Closina 250mg Capsule

Product Type	Single Medicine Product	Effective Date	10/10/2005 1:05:05 PM
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

This product accepted for registration/listing as 'currently supplied' at the time of commencement of the Act. Indications held in ARTG paper records. (Old code)

Specific Indications

Cycloserine is indicated in the treatment of active pulmonary and extra-pulmonary tuberculosis (including renal disease) when the organisms are susceptible to this drug and after failure of adequate treatment with the primary medications (streptomycin, isoniazid, rifampicin and ethambutol). Like all anti-tuberculous drugs, cycloserine should be administered in conjunction with other effective chemotherapy and not as the sole therapeutic agent. Cycloserine may be effective in the treatment of acute urinary tract infections caused by susceptible strains of Gram-positive and Gram negative bacteria, especially Klebsiella/Enterobacter species and Escherichia coli. It is generally no more and may be less effective than other antimicrobial agents in the treatment of urinary tract infections should be considered only when the more conventional therapy has failed and when the organism has been demonstrated to be sensitive to the drug.

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	1 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
100	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Capsule, hard
Route of Administration	Oral



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Visual Identification Size 1 gelatin capsules, opaque red cap, opaque grey body, printed "Lilly F04" in black ink

Active Ingredients

cycloserine 250 mg

Other Ingredients (Excipients)

- brilliant scarlet 4R
- butan-1-ol
- ethanol
- Gelatin
- iron oxide black
- iron oxide yellow
- isopropyl alcohol
- potassium hydroxide
- propylene glycol
- purified talc
- purified water
- Shellac
- strong ammonia solution
- titanium dioxide

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