



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	28633	CAPASTAT capreomycin 1g (as sulfate) powder for injection vial
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 . Capastat powder for injection vial

Product Type	Single Medicine Product	Effective Date	3/07/2002
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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

Capreomycin, which is to be used concomitantly with other appropriate antituberculosis agents, is indicated in pulmonary infections caused by capreomycin-susceptible strains of M.tuberculosis when the primary agents (isoniazid, rifampicin, ethambutol, aminosalicylic acid and streptomycin) have been ineffective or cannot be used because of toxicity or the presence of resistant tubercle bacilli. Susceptibility studies should be performed to determine the presence of a capreomycin-susceptible strain of M.tuberculosis.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1g X 1	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Injection, powder for
Route of Administration	Intramuscular
Visual Identification	A white lyophilised powder



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Active Ingredients

capreomycin

1 g

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