Public Summary

Summary for ARTG Entry:	94243 CEFOTAXIME HEXAL INJECTION cefotaxime 500mg (as sodium) powder for injection vial
ARTG entry for	Medicine Registered
Sponsor	Lupin Australia Pty Limited
Postal Address	Suite 2 Level 2 19-23 Prospect Street, Box Hill, VIC, 3128 Australia
ARTG Start Date	27/07/2004
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 . CEFOTAXIME HEXAL cefotaxime 500mg (as sodium) powder for injection vial

Product Type	Single Medicine Product	**Effective Date**	26/07/2004

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

Cefotaxime Hexal Injection is indicated for the treatment of the following types of infection when caused by susceptible micro-organisms. Infections of the respiratory tract (upper and lower). Infections of the urinary tract. Septicaemia - concomitant therapy with an aminoglycoside may be instituted prior to isolation of the causative organism. Intra-abdominal infection. Gonorrhoea (including gonorrhoea caused by beta-lactamase producing strains of N. gonorrhoeae.) Ear, nose and throat (ENT) infections. Skin and skin structure infections. Bone and joint infections. Meningitis - Cefotaxime should be combined with an appropriate alternative antibiotic (ampicillin, chloramphenicol or penicillin G) for initial therapy in children, (excluding neonates), pending the availability of culture and sensitivity results. In adults the empirical use of cefotaxime should be restricted to patients suspected of having meningitis caused by gram-negative enteric bacilli. Cefotaxime Hexal Injection may be used for the prevention of post-operative infection in obstetric surgery, vaginal and abdominal hysterectomy and biliary surgery. In serious cases, Cefotaxime Hexal Injection may be used, if considered appropriate, before the results of sensitivity tests become available. The emergence of resistance to cefotaxime may complicate treatment.

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	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
1 VIAL	(S4) Prescription Only Medicine
10 VIALS	(S4) Prescription Only Medicine

Components

1 . Medicine Component

Dosage Form	Injection, powder for
Route of Administration	Intravenous

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Visual Identification	Clear glass vial containing a white to slightly yellow powder.

Active Ingredients	
cefotaxime sodium	**524 mg**
Equivalent: cefotaxime	500 mg

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