



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 120543 CEFTAZIDIME JUNO ceftazidime (as pentahydrate) 1g powder for injection vial

ARTG entry for Medicine Registered
Sponsor Juno Pharmaceuticals Pty Ltd
Postal Address Level 2 6 Bond Street, South Yarra, VIC, 3141
 Australia
ARTG Start Date 19/09/2006
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. CEFTAZIDIME JUNO ceftazidime (as pentahydrate) 1g powder for injection vial

Product Type	Single Medicine Product	Effective date	5/04/2017
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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

CEFTAZIDIME JUNO is indicated for the treatment of single and mixed infections caused by susceptible aerobic organisms with suspected or documented resistance to other antimicrobials, but not ceftazidime, and as an alternative to aminoglycosides in pseudomonal infection in patients in whom aminoglycoside toxicity is a cause for concern and other antibiotics cannot be used. Indications include: Severe infections in general: for example septicaemia, including neonatal sepsis, bacteraemia, and in patients in intensive care units with specific problems, e.g., infected burns. Respiratory tract infections: for example, pneumonia, broncho-pneumonia, infected pleurisy, infected bronchiectasis and bronchitis. Severe ear, nose and throat infections: for example: otitis media, mastoiditis. Urinary tract infections: for example, acute and chronic pyelonephritis, pyelitis, cystitis, urethritis (bacterial only), and infections associated with bladder and renal stones. Skin and soft tissue infections: for example, erysipelas, abscesses, cellulitis, infected burns and wounds, mastitis. Gastrointestinal and abdominal infections: for example, intra-abdominal abscesses, enterocolitis. Bone and joint infections: for example, osteitis, osteomyelitis, septic arthritis, infected bursitis.

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 III Clear	3 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
5 pack	(S4) Prescription Only Medicine
10 pack	(S4) Prescription Only Medicine
Single pack	(S4) Prescription Only Medicine

Components

1. CEFTAZIDIME JUNO ceftazidime (as pentahydrate) 1g powder for injection vial

Dosage Form Injection, powder for

Route of Administration Intramuscular

Intravenous

White or cream coloured powder supplied in 10 mL capacity colourless,

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Visual Identification

Type III glass vials, and sealed with Helvoet Pharma FM257/2 dark grey bromobutyl rubber stopper and violet aluminium flip-off cap.

Active Ingredients

ceftazidime pentahydrate

1.164 g

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