# Public Summary

**Summary for ARTG Entry:** 120544 CEFTAZIDIME JUNO ceftazidime (as pentahydrate) 2g powder for injection vial

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| **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) 2g powder for injection vial

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

**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**

Single pack

**Poison Schedule**

(S4) Prescription Only Medicine

**Components**

**1. CEFTAZIDIME JUNO ceftazidime (as pentahydrate) 2g powder for injection vial**

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|---|---|
| **Dosage Form** | Injection, powder for |
| **Route of Administration** | Intravenous |
| **Visual Identification** | White or cream coloured powder supplied in 50 mL capacity colourless, Type III glass vials, and sealed with Helvoet Pharma FM257/2 dark grey bromobutyl rubber stopper and dark green aluminium flip-off cap. |

**Active Ingredients**

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|---|---|
| **ceftazidime pentahydrate** | **2.328 g** |



Public Summary