



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

**Summary for ARTG Entry:** 235010 NEZOLID linezolid 600 mg/300 mL injection solution bag

**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** 28/01/2016  
**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. NEZOLID linezolid 600 mg/300 mL injection solution**

**Product Type** Single Medicine Product **Effective date** 23/05/2017

**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**

Linezolid is indicated for the treatment of suspected or proven infections due to Gram positive organisms resistant to multiple classes of antibiotics, including methicillin resistant Staphylococcus species and vancomycin resistant Enterococcus species. Linezolid is active against Gram-positive bacteria only. Linezolid has no clinical activity against Gram-negative pathogens. Specific Gram-negative therapy is required if a concomitant Gram-negative pathogen is documented or suspected.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bag	PE	36 Months	Store below 25 degrees Celsius	Not recorded	Protect from Light Do not Freeze

**Pack Size/Poison information**

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

**Components**

1. NEZOLID linezolid 600 mg/300 mL injection solution

**Dosage Form**

Injection, solution

**Route of Administration**

Intravenous Infusion

**Visual Identification**

Clear, colourless to yellow solution, free from visible particulates

**Active Ingredients**

Linezolid 600 mg

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