



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 241214 TOBRAMYCIN AN tobramycin 300 mg/5 mL inhalation solution ampoule

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 13/04/2016
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. TOBRAMYCIN AN tobramycin 300 mg/5 mL inhalation solution ampoule

Product Type	Single Medicine Product	Effective date	26/05/2016
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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

Tobramycin solution for inhalation is indicated for the management of cystic fibrosis patients with P. aeruginosa infections. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 \geq 25 % or \geq 80 % predicted at screening, or patients colonized with Burkholderia cepacia (see CLINICAL TRIALS).

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	LDPE	24 Months	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	56	Poison Schedule	(S4) Prescription Only Medicine
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Components

1. TOBRAMYCIN AN tobramycin 300 mg/5 mL inhalation solution ampoule

Dosage Form	Inhalation, conventional
Route of Administration	Inhalation
Visual Identification	A clear, colorless to slightly yellow solution packaged in a clear ampoule.

Active Ingredients

Tobramycin	60 mg/mL
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