



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 238265 ZOLFEND voriconazole 200 mg 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 22/07/2016
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. ZOLFEND voriconazole 200 mg powder for injection vial

Product Type	Single Medicine Product	Effective date	28/10/2016
---------------------	-------------------------	-----------------------	------------

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

Voriconazole is indicated for treatment of the following fungal infections: Invasive aspergillosis. Serious Candida infections (including C. krusei), including oesophageal and systemic Candida infections (hepatosplenic candidiasis, disseminated candidiasis, candidaemia). Serious fungal infections caused by Scedosporium spp and Fusarium spp. Other serious fungal infections, in patients intolerant of, or refractory to, other therapy. Prophylaxis in patients who are at high risk of developing invasive fungal infections. The indication is based on studies including patients undergoing haematopoietic stem cell transplantation.

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	36 Months	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
1	(S4) Prescription Only Medicine

Components

1. ZOLFEND voriconazole 200 mg powder for injection vial

Dosage Form Injection, powder for

Route of Administration Intravenous

Intracranial

Visual Identification White to off white lyophilized powder

Active Ingredients

Voriconazole 200 mg

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary