



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

**Public Summary**

**Summary for ARTG Entry:** 203825 ESOMEPRAZOLE AN esomeprazole (as sodium) 40 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** 30/01/2014  
**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. ESOMEPRAZOLE AN esomeprazole (as sodium) 40 mg powder for injection vial**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	24/10/2018
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**Permitted Indications**

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

The short-term management of Gastro-Oesophageal Reflux Disease (GORD) in patients with oesophagitis and/or severe symptoms of reflux as an alternative when oral therapy is inappropriate.,Prevention of rebleeding in patients following therapeutic endoscopy for acute, bleeding gastric or duodenal ulcers.,Short-term management in patients requiring continued non-steroidal anti-inflammatory drug (NSAID) therapy when oral therapy is inappropriate.,? healing of gastric ulcers associated with NSAID therapy.,? prevention of gastric and duodenal ulcers associated with NSAID therapy, in patients at risk,esomeprazole IV should be replaced with oral therapy as soon as practicable.

**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	2 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
50 x 10mL	(S4) Prescription Only Medicine
10 x 10mL	(S4) Prescription Only Medicine

**Components**

**1. ESOMEPRAZOLE AN esomeprazole (as sodium) 40 mg powder for injection vial**

<b>Dosage Form</b>	Injection, powder for
<b>Route of Administration</b>	Intravenous
<b>Visual Identification</b>	Vial containing a white or almost white porous lyophilised powder.

**Active Ingredients**

esomeprazole sodium	<b>42.5 mg</b>
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