



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

**Public Summary**

**Summary for ARTG Entry:** 224246 MORPHINE JUNO morphine hydrochloride trihydrate 10 mg/1 mL solution for injection 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** 6/05/2015  
**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. MORPHINE JUNO morphine hydrochloride trihydrate 10 mg/1 mL solution for injection ampoule**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	18/08/2016
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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**

Morphine hydrochloride is indicated for the relief of moderate to severe pain not responsive to non-opioid analgesics, symptomatic relief of severe and intractable pains of various categories, in terminal cancer patients and use as a pre-operative medication and as an analgesic adjunct in general anaesthesia.

**Warnings**

See Product Information and Consumer Medicine Information for this product

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	Glass Type I Coloured	24 Months	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>
5 and 10	(S8) Controlled Drug

**Components**

**1. MORPHINE JUNO morphine hydrochloride 10 mg/1 mL solution for injection ampoule**

<b>Dosage Form</b>	Injection, solution
<b>Route of Administration</b>	Intramuscular Intravenous Infusion Subcutaneous
<b>Visual Identification</b>	Clear colourless to pale yellow solution in a yellow ampoule

**Active Ingredients**

morphine hydrochloride trihydrate	<b>10 mg/mL</b>
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