



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 224251 MORPHINE JUNO morphine hydrochloride trihydrate 50 mg/5 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 50 mg/5 mL solution for injection ampoule

Product Type	Single Medicine Product	Effective date	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

Pack Size	Poison Schedule
5 and 10	(S8) Controlled Drug

Components

1. MORPHINE JUNO morphine hydrochloride 50 mg/5 mL solution for injection ampoule

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

Active Ingredients

morphine hydrochloride trihydrate	10 mg/mL
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