



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 279328 Oxycodone Juno oxycodone hydrochloride 50 mg / 1 mL solution for infusion 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 31/08/2017
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. Oxycodone Juno oxycodone hydrochloride 50 mg / 1 mL solution for infusion ampoule

Product Type	Single Medicine Product	Effective date	31/08/2017
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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

The management of opioid-responsive, moderate to severe pain.

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 Clear	3 Years	Store below 30 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
5 ampoules	(S8) Controlled Drug

Components

1. Oxycodone Juno oxycodone hydrochloride 50 mg / 1 mL solution for infusion ampoule

Dosage Form Injection, solution

Route of Administration Intravenous

Subcutaneous

Visual Identification Clear and colourless solution

Active Ingredients

oxycodone hydrochloride 50 mg

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