



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

**Public Summary**

**Summary for ARTG Entry:** 202840 TRAMADOL AN tramadol hydrochloride 100 mg/2 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** 28/01/2014  
**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. TRAMADOL AN tramadol hydrochloride 100 mg/2 mL solution for injection ampoule**

<b>Product Type</b>	Single Medicine Product	<b>Effective date</b>	27/09/2018
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**Permitted Indications**

**Indication Requirements**

No Indication Requirements included on Record

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

Relief of 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**

5 ampoules x 2mL

**Poison Schedule**

(S4) Prescription Only Medicine

**Components**

1. TRAMADOL AN tramadol hydrochloride 100 mg/2 mL solution for injection ampoule

**Dosage Form**

Injection, solution

**Route of Administration**

Intramuscular  
 Intravenous

**Visual Identification**

Ampoule containing a transparent, colourless or slightly yellowish solution

**Active Ingredients**

Tramadol hydrochloride	<b>100 mg</b>
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Public Summary

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