Public Summary

Summary for ARTG Entry: 211626 KETOROLAC JUNO ketorolac trometamol 30 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	20/08/2014
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. KETOROLAC JUNO ketorolac trometamol 30 mg/1 mL solution for injection ampoule

Product Type Single Medicine Product **Effective date** 11/02/2019

Permitted Indications

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Ketorolac trometamol solution for injection is indicated for the short-term management of moderately severe, acute pain following surgical procedures. The total duration of ketorolac use should not exceed five days.,It is recommended that ketorolac parenteral be used in the immediate post-operative period.,Patients can then be converted to the oral formulation (dependent on their analgesic needs), as outlined in the "DOSAGE AND ADMINISTRATION" Section (Refer to "Conversion from Parenteral to Oral Therapy"). The total period of treatment utilising the oral and/or intramuscular route of administration is not to exceed five days. Note that oral dosage form can be available from other brand/s.,General,Ketorolac trometamol solution for injection is not recommended for use as an obstetrical pre-operative medication or for obstetrical analgesia because it has not been adequately studied for use in these circumstances and because the known effects of drugs that inhibit prostaglandin biosynthesis on uterine contraction and foetal circulation.,There is no satisfactory evidence for the use of ketorolac trometamol solution for injection in acute exacerbations of chronic painful inflammatory conditions (e.g. rheumatoid or osteoarthritis).

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

Pack Size/Poison information

Pack Size	Poison Schedule
100 ampoules	(S4) Prescription Only Medicine
5 ampoules	(S4) Prescription Only Medicine

Components

1. KETOROLAC JUNO ketorolac trometamol 30 mg/1 mL solution for injection ampoule

Dosage Form	Injection, solution
Route of Administration	Intramuscular
Visual Identification	Clear and colourless or slightly yellow solution

Active Ingredients

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ketorolac trometamol	**30 mg**

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