



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 209216 TIROFIBAN JUNO tirofiban (as hydrochloride) 12.5mg/50mL Concentrated Injection for infusion Vial

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 9/05/2014
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. TIROFIBAN JUNO tirofiban (as hydrochloride) 12.5mg/50mL Concentrated Injection for infusion Vial

Product Type	Single Medicine Product	Effective date	20/08/2015
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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

TIROFIBAN JUNO, in combination with heparin, is indicated for patients with unstable angina or non-Q-wave myocardial infarction to prevent cardiac ischaemic events. (See PHARMACOLOGY and DOSAGE AND ADMINISTRATION.)

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	3 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Protect from Light Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1 vial	(S4) Prescription Only Medicine

Components

1. TIROFIBAN JUNO tirofiban (as hydrochloride) 12.5mg/50mL Concentrated Injection for infusion Vial

Dosage Form	Injection, concentrated
Route of Administration	Intravenous
Visual Identification	A clear, colourless sterile solution. Practically free from visible particles
Active Ingredients	
tirofiban hydrochloride	14.05 mg

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