



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 222348 TRANEXAMIC ACID JUNO tranexamic acid 1000 mg/10 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 2/03/2015
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. TRANEXAMIC ACID JUNO tranexamic acid 1000 mg/10 mL solution for injection ampoule

Product Type	Single Medicine Product	Effective date	17/08/2016
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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

Adults

For the reduction of peri- and post-operative blood loss and the need for blood transfusion in patients undergoing cardiac surgery or total knee arthroplasty or total hip arthroplasty.

Paediatrics

For the reduction of peri- and post-operative blood loss and the need for blood transfusion in patients undergoing cardiac surgery.

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	24 Months	Store below 25 degrees Celsius	Not recorded	Do not Freeze Protect from Light

Pack Size/Poison information

Pack Size

10

1

Poison Schedule

(S4) Prescription Only Medicine

(S4) Prescription Only Medicine

Components

1. TRANEXAMIC ACID JUNO tranexamic acid 1000 mg/10 mL solution for injection ampoule

Dosage Form

Injection, solution

Route of Administration

Intravenous

Visual Identification

It is a sterile, clear, colourless solution, practically free from visible particles.

Active Ingredients

Tranexamic acid

1000 mg

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