

Public Summary

Summary for ARTG Entry: 25347 FRAGMIN dalteparin sodium 2,500 anti-Xa IU/0.2mL injection syringe

ARTG entry for Medicine Registered
Sponsor Pfizer Australia Pty Ltd
Postal Address 38-42 Wharf Road, WEST RYDE, NSW, 2114
 Australia
ARTG Start Date 21/10/1991
Product category Medicine
Status Active
Approval area Drug Safety Evaluation Branch

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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. FRAGMIN dalteparin sodium 2,500 Anti-Xa IU/0.2mL injection syringe

Product Type	Effective date
Single Medicine Product	10/06/2016

Warnings

See Product Information and Consumer Medicine Information for this product

Standard Indications

Specific Indications

Prophylaxis against thrombotic complications during haemodialysis and treatment of acute deep vein thrombosis (DVT). Extended treatment of symptomatic venous thromboembolism (VTE) (proximal deep vein thrombosis and/or pulmonary embolism) to reduce the recurrence of VTE in patients with solid tumour cancers. Treatment of unstable coronary artery disease, i.e. unstable angina and non-ST-elevation myocardial infarction (also known as non-Q-wave myocardial infarction). Prophylaxis against thrombo-embolic complications in the peri- or postoperative period of surgery.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size

10 x 0.2mL

5 x 0.2mL

Components

1. Medicine Component

Dosage Form

Route of Administration

Visual Identification

Active Ingredients

Dalteparin sodium

Poison Schedule

(S4) Prescription Only Medicine

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Injection, solution

Subcutaneous

Intravenous

A clear colourless or straw coloured solution

2500 anti-Xa IU