Public Summary

Summary for ARTG Entry: 66626 FRAGMIN dalteparin sodium 10,000 anti-Xa IU/1mL injection syringe (graduated)

ARTG entry for	Medicine Registered
Sponsor	Pfizer Australia Pty Ltd
Postal Address	38-42 Wharf Road, WEST RYDE, NSW, 2114 Australia
ARTG Start Date	23/11/1998
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. FRAGMIN dalteparin sodium 10,000 Anti-XaIU/1mL injection syringe (graduated)

Product Type Single Medicine Product **Effective date** 13/11/2017

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

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.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Syringe	Glass	3 Years	Store below 25 degrees Celsius	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
5 x 1.0mL	(S4) Prescription Only Medicine
2 x 1.0mL	(S4) Prescription Only Medicine
10 x 1.0mL	(S4) Prescription Only Medicine
6 x 1.0mL	(S4) Prescription Only Medicine
15 x 1.0mL	(S4) Prescription Only Medicine

Components

1. Medicine Component

Dosage Form	Injection, solution
Route of Administration	Subcutaneous Intravenous
Visual Identification	A clear colourless or straw-coloured solution.

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Active Ingredients	
Dalteparin sodium	**10000 anti-Xa IU/mL**

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