



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 241714 Bivalirudin APOTEX bivalirudin (as trifluoroacetate) 250mg powder for injection vial

ARTG entry for Medicine Registered
Sponsor Apotex Pty Ltd
Postal Address PO Box 280, NORTH RYDE BC, NSW, 1670
 Australia
ARTG Start Date 17/05/2016
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. Bivalirudin APOTEX bivalirudin (as trifluoroacetate) 250mg powder for injection vial

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

Bivalirudin is indicated for use as an anticoagulant:

- in the treatment of patients with moderate to high risk acute coronary syndromes (ACS) (unstable angina/non-ST segment elevation myocardial infarction (UA/NSTEMI) who are undergoing early invasive management, and
- in patients undergoing percutaneous coronary intervention (PCI).

Bivalirudin is intended for use with aspirin.
 A P2Y12 antagonist (e.g. clopidogrel or ticlopidine) may be used in addition to aspirin.

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	24 Months	Store below 25 degrees Celsius	Not recorded	Store in Original Container

Pack Size/Poison information

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

Components

1. Bivalirudin APOTEX bivalirudin (as trifluoroacetate) 250mg powder for injection vial

Dosage Form Injection, powder for
Route of Administration Intravenous
Visual Identification White to off-white lyophilisate powder

Active Ingredients

Bivalirudin **250 mg**

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