

Bivalirudin APOTEX Powder for Injection

Contains the active ingredient bivalirudin (as trifluoroacetate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about Bivalirudin powder for injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Bivalirudin APOTEX Powder for Injection. It contains the active ingredient bivalirudin.

Bivalirudin is a medicine that stops blood clotting (an anticoagulant). It helps prevent unwanted blood clotting during an "angioplasty".

"Angioplasty" is the name of the medical procedure in which blocked blood vessels in the heart are unblocked. Angioplasty is also called "percutaneous coronary intervention (PCI)". Angioplasty improves blood flow in the heart. Angioplasty helps heart problems such as angina. Your doctor unblocks the blood vessels in the heart using a fine tube inserted through a blood vessel in the skin.

You need an anticoagulant during an angioplasty/PCI, to stop unwanted blood clotting. Bivalirudin may also be given to you in hospital before angioplasty/PCI.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

A protein called "thrombin", starts blood clotting. Bivalirudin is an anticoagulant. It prevents blood clotting by stopping thrombin from working.

Use in children

The safety and effectiveness of this medicine has not been studied in children.

Before you are given this medicine

When you must not be given it

You must not be given this medicine if:

- **You have or have had any of the following:**

- Active bleeding or increased risk of bleeding because of haemostasis disorders and/or irreversible coagulation disorders
- Severe uncontrolled hypertension
- Subacute bacterial endocarditis.

- **You are hypersensitive to, or have had an allergic reaction to, bivalirudin or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, tightness of the chest, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you are given it

Before you are given this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - tend to bleed or bruise easily
 - have kidney or liver disease
 - have uncontrolled high blood pressure
 - have any other heart condition.
3. You are currently pregnant or you plan to become pregnant. Your doctor should have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breast-feed. It is not known whether this medicine passes into human breast milk.

Your risk of bleeding may increase:

- if you have recently given birth or if you are pregnant
- if you are already taking medicines, especially blood-thinners/anticoagulants.

Some medicines may interact with bivalirudin.

These include:

- other medicines use to stop blood clotting (anticoagulants), such as warfarin, or heparin
- medicines which affect platelets, (platelets are blood particles involved in clotting). Examples are aspirin, ticlopidine or clopidogrel
- self-administered non-prescription medicines, such as St John's Wort, ginseng and ginkgo biloba.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with bivalirudin.

How this medicine is given

Your doctor will give you bivalirudin into a vein as an injection and/or as a continuous infusion.

During percutaneous coronary intervention (PCI, angioplasty), bivalirudin should be given with aspirin.

How much is given

Your doctor will decide how much of this medicine you will receive.

If you have kidney disease your doctor may change the usual dose.

If you receive too much (overdose)

As bivalirudin is given to you in a hospital under the supervision of your doctor or medical staff, it is very unlikely that you will receive an overdose. You will be closely monitored while in the hospital so that any unwanted side effects can be treated. However if you experience severe side effects tell your doctor immediately.

Possible side effects

Tell your doctor as soon as possible if you do not feel well after you have been given bivalirudin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Allergic reactions

If you think you are having an allergic reaction to bivalirudin, contact your medical or nursing staff immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- tightness of the chest
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Tell your doctor if you notice any of the following:

- bleeding from other parts of the body
- nausea
- headache
- vomiting
- trouble falling asleep
- low blood pressure
- high blood pressure
- fever
- pain, at injection site, chest or back
- heart beat too slow, or too fast
- skin rash
- anaemia, decreased platelets, blood vessel disorders.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- bleeding for example at needle puncture wounds, into the urine, or bruising where the intravenous catheter was inserted.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

This medicine will be stored in the pharmacy or on the ward. It is kept in a cool dry place where the temperature stays below 25°C

After bivalirudin powder has been dissolved, use the solution as soon as possible.

NOTE: the dissolved bivalirudin solution can be stored for up to 24 hours between 2°C and 8°C (the temperature of most standard refrigerators).

DO NOT FREEZE.

Do not place in a freezer or freezing compartment of a refrigerator.

Disposal

Bivalirudin is used for one dose in one patient only. Any remaining contents should be discarded.

Product description

What Bivalirudin APOTEX powder for injection looks like

Bivalirudin powder for injection is a white to off-white lyophilisate powder for reconstitution for i.v. injection and is supplied in a glass vial.

Ingredients

Each vial contains 250 mg of bivalirudin (as trifluoroacetate) as the active ingredient.

It also contains the following inactive ingredients:

- mannitol
- sodium hydroxide

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

Bivalirudin APOTEX 250 mg powder for injection (clear glass vial):
AUST R 241714.

Sponsor

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