

ANGIOMAX®

Bivalirudin (Bye-val-eh-roo-din)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ANGIOMAX®.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you having ANGIOMAX® against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ANGIOMAX® is used for

ANGIOMAX® (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 to the heart muscle. Angioplasty helps heart problems such as angina. Your doctor unblocks the blood vessels in the heart using a fine tube (catheter) inserted through a blood vessel in the skin.

You need an anticoagulant during an angioplasty/PCI to stop unwanted blood clotting.

Angiomax® may also be given to you in hospital before and after angioplasty/PCI.

Ask your doctor if you have any questions about why ANGIOMAX® has been prescribed for you.

There is no information from clinical studies on the safety and effectiveness of ANGIOMAX® in children.

ANGIOMAX® is a “PRESCRIPTION ONLY MEDICINE”. Use only for the person for whom it has been prescribed.

How ANGIOMAX® works

A protein, called “thrombin”, starts blood clotting.

ANGIOMAX® is an anticoagulant. It prevents blood clotting by stopping thrombin from working. This effect gradually wears off after about two hours in most people.

Before you are given ANGIOMAX®

When you must not be given ANGIOMAX®

You must not be given ANGIOMAX® if you are allergic to:

- ANGIOMAX® or any other medicine containing bivalirudin

- other ingredients in ANGIOMAX® (mannitol and sodium hydroxide)

Symptoms of an allergic reaction may include:

- shortness of breath, tightness of the chest, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

You must not be given ANGIOMAX® if you:

- **have, or have recently had, any bleeding from your stomach, intestines, bladder or other organs, for example, if you have noticed abnormal blood in your stools or urine (except from menstrual bleeding)**
- **have severe uncontrolled high blood pressure**
- **have inflammation of the heart tissue (endocarditis)**
- **have severe kidney problems (such as kidney failure) or are on dialysis**

Before ANGIOMAX® is given

Before you are given ANGIOMAX®, it is important for your doctor to know if you have medical problems other than the one ANGIOMAX® is being used for.

Tell your doctor if you:

- tend to bleed or bruise easily
 - have kidney or liver disease
 - have any other heart condition
- Your risk of bleeding may increase:
- if you are already taking medicines, especially blood-

thinners/anticoagulants or medicines to prevent blood clots (anticoagulants or antithrombotics e.g. warfarin, dabigatran, apixaban, rivaroxaban, aspirin (acetylsalicylic acid), clopidogrel, prasugrel, ticagrelor).

- if you have recently given birth or if you are pregnant

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

The active ingredient in ANGIOMAX® could be excreted into breast milk. Your doctor can discuss with you the risks and benefits involved

If you have not told your doctor about any of the above, tell him/her before you are given ANGIOMAX®.

Taking other medicines

Tell your doctor if you are using any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

It may be necessary to change the dose or stop using one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- other medicines used to stop blood clotting (anticoagulants), such as warfarin, or heparin (examples are Coumadin®, Clexane®, Fragmin® or Heparin Injection BP)
- medicines which affect platelets. (Platelets are blood particles involved in clotting.) Examples are aspirin (e.g. Disprin®), ticlopidine or clopidogrel (e.g. Plavix®)
- self-administered non-prescription medicines, such as St John's Wort, ginseng and ginkgo biloba

How will ANGIOMAX® be given

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

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

Your doctor will decide how much Angiomax® to give you.

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

While you are being given ANGIOMAX®

If you are taking warfarin, your doctor may do some blood clotting tests after your treatment with ANGIOMAX®.

Things you must not do

Do not give ANGIOMAX® to anyone else, even if they appear to have the same condition as you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ANGIOMAX®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, tell your medical or nursing staff immediately. (If you have been discharged from hospital, go to

accident and emergency at your nearest hospital)

- **swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing**
- **tightness of the chest, wheezing**
- **itchiness or hives**

These are very serious side effects. If you have them, you may have had a serious allergic reaction to ANGIOMAX®. You may need urgent medical attention or hospitalisation.

ANGIOMAX® (like other anticoagulants), may have unwanted or excessive bleeding as a side effect.

The following unwanted effects have been observed with ANGIOMAX®:

Very Common

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

Common

- bleeding inside other parts of the body or the head
- nausea
- headache
- vomiting
- trouble falling asleep and staying asleep
- low blood pressure
- high blood pressure
- fever
- pain including at injection site, abdomen, chest or back
- heart beat too slow, or too fast
- shortness of breath, difficulty breathing
- skin rash
- anaemia, decreased platelets, blood vessel disorders

Uncommon

- allergic reaction and shock (anaphylaxis)
- non-specified hypersensitivity
- Thrombosis (blood clot) which may result in serious or fatal

complications such as heart attack.

The following side effects have also occurred in some people

- chest pain which may spread to your neck and shoulder
- anxiety and restlessness
- chest discomfort that is relieved by sitting or leaning forward
- fainting, dizziness and loss of consciousness
- Chest discomfort associated with shortness of breath, changing with body movements and body position
- Heart rate changes (decreased, increased or irregular) which should be evaluated by a specialist
- Clotting of blood at the catheter site
- swelling in the blood vessels in the groin at the catheter site
- aching, burning or cramping pain
- bleeding inside the head
- Hives
- Changes in your INR levels (warfarin blood test)

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given ANGIOMAX®

Storage

ANGIOMAX® is usually stored in the clinic.

ANGIOMAX® will be stored below 25°C.

Keep ANGIOMAX® out of reach of children.

After ANGIOMAX® powder has been dissolved, the doctor will use the solution as soon as possible.

NOTE: the dissolved ANGIOMAX® solution can be stored for up to 24 hours at between

2° and 8°C (the temperature of most standard refrigerators).

DO NOT FREEZE.

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

Note the expiry date on the pack.

Do not use after this expiry date.

Product description

What it looks like

ANGIOMAX® is a white sterile powder in single-use, glass vials.

- 250 mg ANGIOMAX® Powder is in a 10 mL vial. It is prepared for use. The contents will be prepared for administration by your healthcare professional.

Ingredients

Active ingredients:

- 250 mg of bivalirudin.

Other ingredients:

- mannitol
- sodium hydroxide

ANGIOMAX® does not contain:

- lactose
- gluten
- preservative

Sponsor/Distributor

ANGIOMAX® is sponsored in Australia by:

The Medicines Company
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