

TIROFIBAN AC

tirofiban hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TIROFIBAN AC.

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 using TIROFIBAN AC against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What is TIROFIBAN AC used for

TIROFIBAN AC, in combination with heparin (another medicine used to prevent blood clots), is used to prevent complications that may occur in people who have unstable angina (a type of chest pain) or are having a heart attack.

TIROFIBAN AC belongs to a group of medicines called platelet aggregation inhibitors. It works by preventing cells in the blood, called platelets, from sticking together to form blood clots. If blood clots are not treated or prevented, they can block blood vessels. This can lead to complications such as angina or heart attacks.

Before you take TIROFIBAN AC

When you must not be given it

Do not use TIROFIBAN AC if you have an allergy to TIROFIBAN AC or any of the ingredients listed at the end of this leaflet.

Do not use TIROFIBAN AC if you have any of the following medical conditions:

- **bleeding inside your body, or a history of increased tendency to bleeding, especially within the last 30 days**
- **a history of bleeding in the brain or brain tumour**
- **a history of abnormal or deformed arteries or veins**
- **a history of swelling and weakening of a part of a blood vessel, also called aneurysm**
- **a history of stroke, especially within the last 30 days, or any history of stroke due to bleeding in the brain**
- **major surgery or physical trauma, including falls or blows to the body or head, especially within the last month**
- **a history, symptoms or signs of aortic dissection, a disease of a large blood vessel**
- **severe, uncontrolled high blood pressure**
- **pericarditis, a condition which involves swelling of the lining that surrounds the heart.**

If you are not sure whether you should start receiving TIROFIBAN AC, talk to your doctor.

Do not use TIROFIBAN AC if you have received TIROFIBAN AC before and developed a low platelet count.

If you are not sure whether you have received TIROFIBAN AC before and developed a low platelet count, ask your doctor.

Do not use TIROFIBAN AC if you are already receiving an injection of another 'platelet aggregation inhibitor' medicine.

Do not use TIROFIBAN AC if you are breast-feeding or intend to breast-feed.

TIROFIBAN AC is not recommended for use while breast-feeding. It is not known whether it passes into breast milk.

Do not use TIROFIBAN AC in children.

The safety and effectiveness in children have not been established.

Before you are given it

Tell your doctor if:

1. **you are pregnant.** Like most medicines, TIROFIBAN AC is generally not recommended during pregnancy. However, if there is a need to consider using TIROFIBAN AC during pregnancy, your doctor will discuss the possible risks and benefits to you and your unborn baby.
2. **you have or have had any medical conditions, especially the following:**
 - any bleeding problems, including stomach bleeding, or blood in your urine or stools, within the last year
 - blood clotting problems or platelet diseases, including low platelet count
 - disease of the blood vessels of the brain, including stroke, within the last year
 - problems with the blood vessels in the back of your eye/s
 - kidney disease, or are undergoing dialysis
3. **you have received platelet aggregation inhibitors before**
4. **you recently had an epidural (spinal) procedure**
5. **you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any of the above, tell them before you are given TIROFIBAN AC.

Taking other medicines

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

Some medicines and TIROFIBAN AC may interfere with each other. This includes:

- medicines used to dissolve or prevent blood clots, including warfarin

These medicines may be affected by TIROFIBAN AC, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given TIROFIBAN AC.

How TIROFIBAN AC is given

TIROFIBAN AC is given as a slow injection into a vein.

TIROFIBAN AC must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive TIROFIBAN AC. This depends on your condition and other factors, such as your weight and kidney function.

Side Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given TIROFIBAN AC.

TIROFIBAN AC helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Tell your doctor or nurse immediately if you notice any unusual bleeding or bruising.

This includes bleeding gums, nose bleeds, blood in your urine, bloody or black, tarry stools, coughing up blood, vomiting blood or material that looks like coffee grounds.

These may be serious side effects of TIROFIBAN AC. You may need urgent medical attention.

Also, tell your doctor or nurse immediately if you notice any of the following:

- rash
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- chills, dizziness, or wheezing

If you have them, you may be having an allergic reaction to TIROFIBAN AC. You may need urgent medical attention.

Tell your doctor or nurse if you notice any of the following and they worry you:

- fever
- nausea
- headache

These are usually mild side effects of TIROFIBAN AC.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

TIROFIBAN AC will be stored in the pharmacy or on the ward.

It is kept in a cool, dry place where it is protected from light and where the temperature stays below 25°C.

Product Description

What it looks like

TIROFIBAN AC comes in a glass vial, containing 50 mL of solution.

Ingredients

Active ingredient:

- 0.25 of tirofiban per mL

Inactive ingredients:

- sodium phosphate - dibasic dehydrate
- mannitol
- water for injections

- pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Supplier

TIROFIBAN AC is supplied by:

Actavis Pty Ltd

Level 5, 117 Harrington Street

The Rocks NSW 2000

Phone 1800 554 414

This leaflet was prepared in January 2014.

AUST R 209216