

Eptifibatide 0.75 mg/ml solution for infusion

eptifibatide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The full name of this medicine is Eptifibatide 0.75 mg/ml solution for infusion, but is referred to as Eptifibatide within this leaflet.

What is in this leaflet

1. What Eptifibatide is and what it is used for
2. What you need to know before you are given Eptifibatide
3. How to use Eptifibatide
4. Possible side effects
5. How to store Eptifibatide
6. Contents of the pack and other information

1. What Eptifibatide is and what it is used for

Eptifibatide contains the active substance eptifibatide, an antithrombotic agent, which inhibits platelet aggregation. This means that it helps to prevent blood clots from forming.

It is used in adults whose heart muscle does not get enough oxygen and nutrition with manifestation of severe coronary insufficiency defined as spontaneous and recent chest pain with abnormalities in cardiac examination or biological changes. It is usually given with aspirin and unfractionated heparin.

2. What you need to know before you are given Eptifibatide

You must not be given Eptifibatide:

- if you are allergic to eptifibatide or any of the other ingredients of this medicine (listed in section 6).
- if you have recently had bleeding from your stomach, intestines, bladder or other organs, for example if you have seen abnormal blood in your stool or urine (except from menstrual bleeding) in the past 30 days.
- if you have had a stroke within the past 30 days or any haemorrhagic stroke (also, be sure your doctor knows if you ever had a stroke).
- if you have had a brain tumour or a condition that affects the blood vessels around the brain.
- if you had a major operation or severe injury during the past 6 weeks.
- if you have or have had bleeding problems.
- if you have or have had difficulty with your blood clotting or a low blood platelet count.

- if you have or have had severe hypertension (high blood pressure).
 - if you have or have had severe kidney or liver problems.
 - if you have been treated with another medicine of the same type as Eptifibatide.
- Please tell your doctor if you have had any of these conditions. If you have any questions, ask your doctor or pharmacist or nurse.

Warnings and precautions

- Eptifibatide is recommended for use only in adult, hospitalised patients in coronary care units.
- Before and during your treatment with Eptifibatide, samples of your blood will be tested as a safety measure to limit the possibility of unexpected bleeding.
- During use of Eptifibatide, you will be checked carefully for any signs of unusual or unexpected bleeding.

Children and adolescents

- Do not use in children or adolescents less than 18 years old.

Other medicines and Eptifibatide

To avoid the possibility of interactions with other medicines please tell your doctor or pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Particularly:

- blood thinners (such as oral anticoagulants) or
- medicines that prevent blood clots, including warfarin, dipyridamole, ticlopidine, aspirin (except those that you may be given as part of Eptifibatide treatment).

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby.

Eptifibatide is not usually recommended for use during pregnancy.

Your doctor will weigh up the benefit to you against the risk to your baby.

If you are breast-feeding a baby, breast-feeding should be interrupted during the treatment period.

Eptifibatide contains sodium

This medicinal product contains 140 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 7% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Eptifibatide

Eptifibatide is given into the vein by direct injection followed by an infusion (drip solution). The dose given is based on your weight. The recommended dose is 180 microgram/kg administered as a bolus (rapid intravenous

injection), followed by an infusion (drip solution) of 2 microgram/kg/minute for up to 72 hours. If you have kidney disease, the infusion dose may be reduced to 1 microgram/kg/minute.

If percutaneous coronary intervention (PCI) is performed during Eptifibatide therapy, the intravenous solution may be continued for up to 96 hours.

You must be given doses of aspirin and heparin (if not contraindicated in your case).

If you have any further questions on the use of this product, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common *May affect more than 1 in 10 people*

- minor or major bleeding, (for example, blood in urine, blood in stool, vomiting blood, or bleeding with surgical procedures)

- anaemia (decreased number of red blood cells)

Common *May affect up to 1 in 10 people*

- inflammation of a vein

Uncommon *May affect up to 1 in 100 people*

- reduction in the number of platelets (blood cells necessary for blood clotting)

- reduced blood flow to the brain

Very rare *May affect up to 1 in 10,000 people*

- serious bleeding (for example, bleeding inside the abdomen, inside the brain, and into the lungs)

- fatal bleeding

- severe reduction in the number of platelets (blood cells necessary for blood clotting)

- skin rash (such as hives)

- sudden, severe allergic reaction

If you notice any signs of bleeding, notify your doctor, pharmacist or nurse immediately. Very rarely, bleeding has become severe and even fatal. Safety measures to prevent this from happening include blood tests and careful checking by the healthcare professionals taking care of you.

If you develop severe allergic reaction or hives, notify your doctor, pharmacist or nurse immediately.

Other events that may occur in patients, who require this type of treatment, include those that are related to the condition you are having treated, such as rapid or irregular heartbeat, low blood pressure, shock or cardiac arrest.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eptifibatide

Keep this medicine out of the sight and reach of children.

Single use only.

Do not use this medicine after the expiry date (EXP) stated on the package and the vial. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Keep the vial in the outer package in order to protect from light. However, protection of Eptifibatide solution from light is not necessary during administration.

Before using, the vial contents should be inspected.

Eptifibatide should not be used if it is noticed that particulate matter or discoloration is present.

Any unused medicine after opening should be thrown away.

Do not throw away any medicines via wastewater or household waste. The hospital staff will properly throw away medicines you no longer use.

6. Contents of the pack and other information

What Eptifibatide contains

- The active substance is eptifibatide. Each ml of solution for infusion contains 0.75 mg of eptifibatide. One vial of 100 ml of solution for infusion contains 75 mg of eptifibatide.

- The other ingredients are citric acid monohydrate, sodium hydroxide and water for injections.

What Eptifibatide looks like and contents of the pack

Eptifibatide solution for infusion: 100 ml vial, pack of one vial.

Eptifibatide is a clear, colourless solution contained in a 100 ml glass vial, which is closed with a chlorobutyl rubber stopper and sealed with a crimped aluminium seal.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Kensington Pharma Ltd,
Unit A Newlands House,
60 Chain House Lane,
Whitestake Preston, Lancashire,
PR4 4LG,
United Kingdom

Manufacturer:
Wave Pharma Limited
Ground Floor
Cavendish House
369 Burnt Oak Broadway
Edgware
HA8 5AW
United Kingdom

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04/2022

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Kensington Pharma Ltd,
Unit A Newlands House,
60 Chain House Lane,
Whitestake Preston, Lancashire,
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Manufacturer:

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