

PACKAGE LEAFLET

Package leaflet: Information for the patient

Eptifibatide Jed 2 mg/ml, solution for injection 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 or hospital pharmacist or nurse.
- If you get side effects talk to your doctor or hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Eptifibatide Jed is and what it is used for

Eptifibatide Jed is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming.

It is used in adults with manifestation of severe coronary insufficiency defined as spontaneous and recent chest pain with electrocardiographic abnormalities or biological changes. It is usually given with aspirin and unfractionated heparin.

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

You must not be given Eptifibatide Jed:

- 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 Jed.

Please tell your doctor if you have had any of these conditions. If you have any questions, ask your doctor or hospital pharmacist or nurse.

Take special care with Eptifibatide Jed:

- Eptifibatide Jed is recommended for use only in adult, hospitalised patients in coronary care units.
- Eptifibatide Jed is not intended for use in children or adolescents less than 18 years of age.
- Before and during your treatment with Eptifibatide Jed, samples of your blood will be tested as a

- safety measure to limit the possibility of unexpected bleeding.
- During use of Eptifibatide Jed, you will be checked carefully for any signs of unusual or unexpected bleeding.

Children and adolescents

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

Other medicines and Eptifibatide Jed

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

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

Pregnancy and breast-feeding

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

Eptifibatide Jed 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 Jed contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 10 ml vial, that is to say essentially 'sodium-free'.

3. How to use Eptifibatide Jed

Eptifibatide Jed 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 Jed therapy, the intravenous solution may be continued for up to 96 hours.

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

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

4. Possible side effects

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

Very common side effects

These 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 side effects

These may affect up to 1 in 10 people

- inflammation of a vein.

Uncommon side effects

These 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 side effects

These 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.

Notify your doctor, hospital pharmacist or nurse immediately, if you notice any signs of bleeding. 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.

Notify your doctor, hospital pharmacist or nurse immediately, if you develop severe allergic reaction or hives.

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, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRAPharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Eptifibatide Jed

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. 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 Jed solution from light is not necessary during administration.

Before using, the vial contents should be inspected.

Eptifibatide Jed will not be used if 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. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Eptifibatide Jed contains

- The active substance is eptifibatide. Each ml of solution for injection contains 2 mg of

- eptifibatide. One vial of 10 ml solution for injection contains 20 mg of eptifibatide.
- The other ingredients are citric acid monohydrate, sodium hydroxide and water for injections.

What Eptifibatide Jed looks like and contents of the pack

Eptifibatide Jed solution for injection: 10 ml vial, pack of one vial.

The clear, colourless or almost colourless solution is contained in a 10 ml glass vial with a rubber stopper and an aluminum flip-off seal.

Marketing Authorisation Holder:

JED Pharma Ltd.
Questum Business Park
South Ballingarrane
Clonmel, Co. Tipperary
E91 V329, Ireland

Manufacturer:

Quercus Labo
Wijmenstraat 21p, 9030 Mariakerke
Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

Denmark	Eptifibatide Ctruz 2 mg/ml, injektionsvæske, opløsning
Finland	Eptifibatide Ctruz 2 mg/ml, injektioneste, liuos
Germany	Eptifibatid Altamedics 2 mg/ml, Injektionslösung
Ireland	Eptifibatide Jed 2 mg/ml, solution for injection
Italy	Eptifbatid Alida
Netherlands	Eptifibatide AFTPharm 2 mg/ml, oplossing voor injectie
Norway	Eptifibatide Ctruz
Sweden	Eptifibatide Ctruz 2 mg/ml, injektionsvätska, lösning

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