PACKAGE LEAFLET

Package leaflet: Information for the patient

Eptifibatide Jed 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 or hospital pharmacist or nurse.
- If you get any 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

Eptifibatide Jed is an inhibitor of 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 (manifestation of severe coronary insufficiency). They then have 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 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 high blood pressure (hypertension).
- 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.

- 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.

3. How to use Eptifibatide Jed

This medicine is for hospital use only. It must be administered by experienced medical staff.

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 per kilogram bodyweight administered as a rapid intravenous injection (bolus), followed by an infusion (drip solution) of 2 microgram per kilogram bodyweight per minute for up to 72 hours. If you have kidney disease, the infusion dose may be reduced to 1 microgram per kilogram bodyweight per 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 *May affect more than 1 in 10 users*
- 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 users*

- inflammation of a vein.

Uncommon *May affect up to 1 in 100 users*
- 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 users*
- 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 HPRA Pharmacovigilance 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 (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 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. The hospital staff will properly throw away medicines you no longer use.

6. Contents of the pack and other information

What Eptifibatide Jed 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 Jed looks like and contents of the pack

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

The clear, colourless or almost colourless solution is contained in a 100 ml glass vial, which is closed with a chlorinated butyl stopper and sealed with a crimped aluminium-plastic flip-off seal.

Marketing Authorisation Holder and manufacturer

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 0,75 mg/ml, infusionsvæske, opløsning
Finland	Eptifibatide Ctruz 0,75 mg/ml, infuusioneste, liuos
Germany	Eptifibatid Altamedics 0,75 mg/ml, Infusionslösung
Ireland	Eptifibatide Jed 0.75 mg/ml, solution for infusion
Italy	Eptifbatid Alida
Netherlands	Eptifibatide AFTPharm 0,75 mg/ml, oplossing voor infusie
Norway	Eptifibatide Ctruz
Sweden	Eptifibatide Ctruz 0,75 mg/ml, infusionsvätska, lösning

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