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INTEGRILIN

2 mg/ml
solution for injection
eptifibatide

Package leaflet: Information for the patient

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 INTEGRILIN IS AND WHAT IT IS USED FOR

Integrilin 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 INTEGRILIN

You must not be given Integrilin:
- 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 Integrilin.

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 Integrilin:
- Integrilin is recommended for use only in adult, hospitalised patients in coronary care units.
- Integrilin is not intended for use in children or adolescents less than 18 years of age.
- Before and during your treatment with Integrilin, samples of your blood will be tested as a safety measure to limit the possibility of unexpected bleeding.
- During use of Integrilin, you will be checked carefully for any signs of unusual or unexpected bleeding.

Other medicines and Integrilin
To avoid the possibility of interactions with other medicines please tell your doctor or hospital pharmacist 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 Integrilin treatment).

Pregnancy and breast-feeding
Integrilin is not usually recommended for use during pregnancy. Tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby. Your doctor will weigh up the benefit to you against the risk to your baby of using Integrilin while you are pregnant.
If you are breast-feeding a baby, breast-feeding should be interrupted during the treatment period.

Integrilin contains sodium
- This medicine contains 13.8 mg sodium (main component of cooking/table salt) in each 10 ml vial. This is equivalent to 0.69% of the recommended maximum daily dietary intake of sodium for an adult.

3. HOW TO USE INTEGRILIN

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

You must also 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 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.

If you notice any signs of bleeding, notify your doctor or hospital 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 or hospital 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, hospital 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 Website: 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 INTEGRILIN

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 Integrilin solution from light is not necessary during administration.

Before using, the vial contents should be inspected.

Integrilin 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. Ask your hospital pharmacist how to throw away medicines you no longer use.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Integrilin 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 Integrilin looks like and contents of the pack
Integrilin solution for injection: 10 ml vial, pack of one vial.

The clear, colourless solution is contained in a 10 ml glass vial, which is closed with a butyl rubber stopper and sealed with a crimped aluminium seal.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder:
GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

Manufacturer:
Glaxo Operations UK Ltd., (Trading as Glaxo Wellcome Operations), Harmire Road, Barnard Castle, Co. Durham, DL12 8DT, United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

United Kingdom
GlaxoSmithKline UK Ltd
Tel: + 44 (0)800 221441
customercontactuk@gsk.com

This leaflet was last revised in 09/2020

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu

Pharma code Ref. No. 7830

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