European Medicines Agency

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Integrilin
eptifibatide

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Integrilin?
Integrilin is a medicine that contains the active substance eptifibatide. It is available as a solution for infusion (drip into a vein) and a solution for injection.

What is Integrilin used for?
Integrilin is used to prevent a myocardial infarction (heart attack) in adults. It is used in the following groups:
- patients who have unstable angina (a severe type of chest pain that varies in intensity);
- patients who have already had a non-Q-wave myocardial infarction (a type of heart attack), with chest pain in the last 24 hours and with abnormalities on the electrocardiogram (ECG) or signs of heart problems in the blood.

Integrilin is given with aspirin and unfractionated heparin (other medicines that prevent blood clots). The patients most likely to benefit from a treatment with Integrilin are those at high risk of myocardial infarction in the three to four days after the start of acute (sudden) angina. This includes patients who are having percutaneous transluminal coronary angiography (PTCA, a type of surgery to clear the arteries supplying the heart).
The medicine can only be obtained with a prescription.

How is Integrilin used?
Integrilin should be given into a vein by a doctor who has experience in the management of heart conditions.
The recommended dose is a single injection of 180 micrograms per kilogram body weight given as soon as possible after diagnosis. This is followed by a continuous infusion of 2.0 microgram/kg per minute which is continued for up to 72 hours, until the start of surgery, or until discharge from the hospital, whichever occurs first.
Patients who have moderate problems with their kidneys should receive a lower dose during the infusion. Integrilin must not be used in patients with severe kidney problems. If the patient undergoes a percutaneous coronary intervention (PCI or angioplasty, a surgical procedure that is used to unblock narrowed coronary arteries), the treatment can be continued for up to 24 hours after surgery, with a maximum treatment duration of 96 hours.

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How does Integrilin work?
Integrilin is an inhibitor of platelet aggregation. This means that it helps to prevent blood clots from forming. When the blood clots, this is due to special cells in the blood called platelets sticking together (aggregating). The active substance in Integrilin, eptifibatide, stops the platelets aggregating by blocking a protein called glycoprotein IIb/III on their surface that helps make them sticky. Integrilin greatly reduces the risk of a blood clot forming and helps prevent another heart attack.

How has Integrilin been studied?
Integrilin has been compared with placebo (dummy treatment) in a study involving 11,000 patients who were in hospital and had signs that they may soon develop a heart attack, or who had already had a small heart attack.
An additional study compared Integrilin with placebo in 2,000 patients who were having PTCA to remove a blood clot from the coronary arteries and insert a stent (a short tube that remains in the artery to stop it closing).
In both studies, patients also received other medicines to prevent the blood clotting. The main measure of effectiveness was the number of patients who had a heart attack or who died within 30 days of treatment.

What benefit has Integrilin shown during the studies?
In the first study, Integrilin was more effective than placebo in preventing death or a heart attack during the 30 days after it was given. A similar benefit was seen in the second study. The main benefit was in the reduction in further heart attacks.

What is the risk associated with Integrilin?
The most common side effect with Integrilin (seen in more than 1 patient in 10) is bleeding, which may be severe. For the full list of all side effects reported with Integrilin, see the Package Leaflet.
Integrilin should not be used in people who may be hypersensitive (allergic) to eptifibatide or any of the other ingredients. It must not be used in patients who have bleeding problems or have a disease that may cause bleeding (such as stroke or severe high blood pressure), or in patients with severe liver or kidney problems. For the full list of restrictions, see the Package Leaflet.

Why has Integrilin been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Integrilin's benefits are greater than its risks when used to prevent early myocardial infarction. The Committee recommended that Integrilin be given marketing authorisation.

Other information about Integrilin:
The European Commission granted a marketing authorisation valid throughout the European Union for Integrilin on 1 July 1999. The marketing authorisation was renewed on 1 July 2004 and on 1 July 2009. The marketing authorisation holder is Glaxo Group Ltd.

The full EPAR for Integrilin can be found here.

This summary was last updated in 07-2009.