

INTEGRILIN

Eptifibatide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about INTEGRILIN.

It does not contain all of the available information.

It does not take the place of talking to your doctor or hospital pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking INTEGRILIN against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or hospital pharmacist.

Keep this leaflet.

You may want to read it again.

What INTEGRILIN is used for

INTEGRILIN works by helping to prevent blood clots by stopping the platelets in the blood from sticking together.

INTEGRILIN is used in people with unstable angina (chest pain) to help prevent heart attack and possible death.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart.

INTEGRILIN is also used to prevent the formation of blood clots when people have a surgical procedure (percutaneous coronary intervention) to open an artery and insert a tube (stent).

Your doctor, however, may prescribe INTEGRILIN for another purpose.

Ask your doctor if you have any questions about why INTEGRILIN has been prescribed for you.

There is no evidence that INTEGRILIN is addictive.

Before you are given INTEGRILIN

When it must not be given

Do not use INTEGRILIN if:

- 1. you are allergic to any ingredients listed at the end of this leaflet.**
- 2. you have any of these medical conditions:**
 - a blood clotting disorder or a very low platelet count
 - a bleeding disorder or you tend to bleed easily
 - very high blood pressure
 - severe liver problems or you require dialysis

- 3. you have had any of these medical conditions:**
 - any internal bleeding (except for menstrual bleeding) in the last month, such as from an ulcer or blood in the urine or bowel motions
 - a stroke as a result of bleeding in the brain
 - any other stroke in the last month
 - surgery or severe injury in the last six weeks
 - any brain tumour or a condition that affects the blood vessels around the brain
- 4. your doctor is going to use either of the following types of medicines:**
 - another injection of the same type as INTEGRILIN
 - medicines used to destroy or dissolve blood clots

INTEGRILIN should not be used in children.

If you are not sure if you should use INTEGRILIN, contact your doctor or hospital pharmacist.

Before you start to use it

You must tell your doctor if:

- you have any other medical conditions including liver or kidney problems or problems with bleeding or blood clots.
- you are pregnant or planning to become pregnant.

Do not use INTEGRILIN if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

If you are breastfeeding, stop breastfeeding while you are being treated with INTEGRILIN.

Taking other medicines

Tell your doctor if you are taking any medicines to thin your blood, to prevent blood clots or to dissolve clots.

Tell your doctor if you are taking any other medicines, including aspirin or other medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Your doctor will usually give you aspirin or heparin at the same time as INTEGRILIN.

How to use INTEGRILIN

INTEGRILIN is given in hospital by an injection into a vein followed by an intravenous drip (infusion). The infusion usually lasts for up to 3 or 4 days.

The dose given is based on your weight. Your doctor or hospital pharmacist will work out the correct dose for you.

You may also be given aspirin and heparin.

If you get too much (overdose)

If you get too much INTEGRILIN, it could cause bleeding. If this happens the intravenous drip may need to be stopped. Usually, this will be enough to handle the overdose. However, if necessary, a blood transfusion may be given.

Contact the Poisons Information Centre for advice regarding management of overdose. In Australia telephone 13 11 26. In New Zealand telephone 0800 POISON or 0800 764 766.

Side effects

Tell your doctor, nurse or hospital pharmacist as soon as possible if you do not feel well while you are being given INTEGRILIN.

Like other medicines, INTEGRILIN may cause some side effects.

Although not all of these side effects may occur, if they do occur they may need medical attention.

The most common side effect experienced by people using this medicine is:

- bleeding
While INTEGRILIN is being used, you will be checked for any signs of unusual or unexpected bleeding.

INTEGRILIN may also cause stinging or redness at the site of injection.

During the administration of INTEGRILIN, the following effects have also occurred in some patients:

- low blood pressure
- abnormal fast heart beat
- congestive heart failure (disease of the heart with shortness of breath or swelling of the feet or legs due to build-up of fluid)
- heart attack
- shock
- swelling and tenderness around a vein
- low number of platelets in blood
- decreased blood flow to brain
- nausea
- headache
- fever
- general body pain
- stomach pain
- chest pain

It is not possible to know whether these effects are related to INTEGRILIN or to the condition INTEGRILIN is used to treat. However, these effects can occur in this condition even without the use of INTEGRILIN.

Other side effects not listed above may also occur in some patients.

If you notice any other effects, check with your doctor.

Ask your doctor or hospital pharmacist any questions you may have.

Storage

INTEGRILIN is stored in a hospital.

It should be stored refrigerated at 2°C to 8°C. Do not freeze. It should be protected from light until administration.

Product description

What it looks like

INTEGRILIN is a clear colourless liquid for injection. It comes in vials in two strengths:

- INTEGRILIN (eptifibatide 20mg in 10mL) Injection
- INTEGRILIN (eptifibatide 75mg in 100mL) Infusion

Ingredients

Active ingredient

- Eptifibatide (as eptifibatide acetate)

Inactive ingredients

- citric acid
- sodium hydroxide
- water for injections

Sponsor

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road,
Macquarie Park NSW 2113,
Australia

and

Merck Sharp & Dohme (New Zealand) Limited

PO Box 99 851
Newmarket
Auckland 1149
New Zealand

Australian Registration Number

- AUST R 71540 (20mg in 10mL)
- AUST R 71541 (75mg in 100mL)

Date of preparation

This leaflet was prepared in July 2014.

140703 v3