INTEGRILIN®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given INTEGRILIN?

INTEGRILIN contains the active ingredient eptifibatide and 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 as well as 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).
For more information, see Section 1. Why am I being given INTEGRILIN? in the full CMI.

2. What should I know before I am given INTEGRILIN?

Do not use if you have ever had an allergic reaction to eptifibatide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I am given INTEGRILIN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INTEGRILIN and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.
Tell your doctor if you are taking any medicines to thin your blood, to prevent blood clots, or to dissolve clots.

4. How is INTEGRILIN given?

- 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.

More instructions can be found in Section 4. How is INTEGRILIN given? in the full CMI.

5. What should I know while being given INTEGRILIN?

Looking after your medicine	• INTEGRILIN is stored in a hospital. • Keep INTEGRILIN refrigerated at 2°C to 8°C. Do not freeze INTEGRILIN. • INTEGRILIN should be protected from light until it is administered.

For more information, see Section 5. What should I know while being given INTEGRILIN? in the full CMI.

6. Are there any side effects?

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

During the administration of INTEGRILIN, the following effects have also occurred in some patients: low blood pressure, abnormal fast heartbeat, 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 and chest pain.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

INTEGRILIN

Active ingredient: *eptifibatide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using INTEGRILIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INTEGRILIN.**

Where to find information in this leaflet:

1. Why am I being given INTEGRILIN?

INTEGRILIN contains the active ingredient eptifibatide.

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.

2. What should I know before I am given INTEGRILIN?

Warnings

Do not use INTEGRILIN if:

- **you are allergic to eptifibatide, or any of the ingredients listed at the end of this leaflet**. Always check the ingredients to make sure you can use this medicine.

- **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
- **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
- **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

Check with your doctor if you:

- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Children

INTEGRILIN should not be used in children.

Addiction

There is no evidence that INTEGRILIN is addictive.

3. What if I am taking other medicines?

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

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INTEGRILIN.

4. How is INTEGRILIN given?

How is it given

- 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 are given too much INTEGRILIN

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.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given INTEGRILIN?

Looking after your medicine

- INTEGRILIN is typically stored in a hospital.
- Keep INTEGRILIN refrigerated at 2°C to 8°C. Do not freeze INTEGRILIN.
- INTEGRILIN should be protected from light until it is administered.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any 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.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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.

Most common side effects

Most common side effects	**What to do**
The most common side effect experienced by people using this medicine is: • bleeding	**Speak to your doctor if you have any of these common side effects and they worry you.**

Other Undesirable Side Effects

Other undesirable side effects	**What to do**
During the administration of INTEGRILIN, the following effects have also occurred in some patients: • low blood pressure • abnormal fast heartbeat	**Tell your doctor, nurse or hospital pharmacist as soon as possible if you do not feel well while you are being given INTEGRILIN**

Other undesirable side effects	What to do
• 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.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INTEGRILIN contains

Active ingredient **(main ingredient)**	eptifibatide (as eptifibatide acetate)
Other ingredients **(inactive ingredients)**	citric acid sodium hydroxide water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What INTEGRILIN looks like

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

INTEGRILIN (eptifibatide 20mg in 10mL) Injection (AUST R 71540)

INTEGRILIN (eptifibatide 75mg in 100mL) Infusion (AUST R 71541)

Who distributes INTEGRILIN

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road,

Macquarie Park NSW 2113, Australia

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