RAPILYSIN

RAP-EE-LIE-SIN

contains the active ingredient reteplase

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RAPILYSIN injection.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RAPILYSIN against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What RAPILYSIN is used for

RAPILYSIN contains the active ingredient reteplase.

RAPILYSIN is used to treat acute myocardial infarctions (also called "heart attacks"). This condition occurs when the blood flow to part of the heart is blocked.

This blockage causes that part of the heart muscle (called the myocardium) to start to die.

RAPILYSIN works by dissolving the blood clot that is blocking your heart blood vessel. It is best given within six hours of the start of any heart symptoms.

If a myocardial infarction is not treated quickly, then it may lead to minor to severe heart damage and sometimes, death.

There are many different types of medicines used to treat myocardial infarctions.

RAPILYSIN belongs to a group of medicines called thrombolytics.

RAPILYSIN is related to a normal substance found in the blood. RAPILYSIN only acts for a short period of time to dissolve clots.

Your doctor, however, may have prescribed RAPILYSIN for another purpose.

Ask your doctor if you have any questions about why RAPILYSIN has been prescribed for you.
This medicine is available only with a doctor's prescription.

Before you are given RAPILYSIN

When you must not have RAPILYSIN

Do not use RAPILYSIN if:

1. **you have had an allergic reaction to RAPILYSIN or any ingredients listed at the end of this leaflet**
2. **you have had prolonged heart massage (also called CPR) in the last 10 days**
3. **you have a tendency for bleeding, either easily caused or slow in stopping**
4. **you are being treated with anticoagulant medicines (used to thin the blood and prevent clots) such as warfarin (Marevan®, Coumadin®) or phenindione (Dindevan®)**
5. **you have a growth, cancer or blood vessel problems within your head**
6. **you have previously had a stroke**
7. **you currently have very high blood pressure**
8. **you have an active ulcer in your stomach or intestine**
9. **you have poor blood flow through the liver (called portal hypertension)**
10. **you have severe liver or kidney problems**
11. **you have inflammation of your pancreas or the area around your heart, or an infection affecting your heart**
12. **you have bleeding behind or in the eye**
13. **you have recently (in the last 3 months) had:**
    - severe bleeding
    - a major physical injury
    - major surgery
    - given birth
    - had a part of a body organ tested (biopsied)
    - had a needle in a major blood vessel.
14. **the package is torn or shows signs of tampering.**

If you are not sure if you should be having RAPILYSIN, talk to your doctor.

Do not give RAPILYSIN to children.
Safety and effectiveness in children have not been established.

Before you are given it

Tell your doctor if:

1. **you are pregnant.**
   RAPILYSIN is not generally recommended for use in pregnant women unless the benefits of treatment outweigh the risk to the unborn baby.
2. **you have any other health problems, especially the following:**
   - a stroke, shock or apoplexy (apoplexy: sudden loss of consciousness followed by paralysis)
   - dizziness or blacking-out spells
   - high blood pressure
   - recent bleeding from your stomach, bowel or genitals, or blood in your urine.
3. **you are allergic to any other medicines, foods, dyes or preservatives.**
4. **you are older than 75 years of age.**
5. **you are breast-feeding or intend to breast-feed.**
   It is not known whether RAPILYSIN passes into breast milk. You should discard any breast milk for 24 hours after the injections.

If you have not told your doctor about any of the above, tell them before you start taking RAPILYSIN.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with RAPILYSIN. These medicines include:

- heparin, enoxaparin (Lovenox®, Clexane®), nadroparin (Fraxiparine®), danaparoid (Orgaran®), abciximab (ReoPro®) or tirofiban (Aggrastat®) injections
- warfarin or phenindione tablets (Marevan®, Coumadin®, Dindevan®)
- aspirin tablets or capsules
- dipyridamole tablets (Persantin®)
- ticlopidine tablets (Ticlid®)
- clopidogrel tablets (Isocover®, Plavix®)
- any other medicines you may be taking to prevent clotting

These medicines may be affected by RAPILYSIN, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid during your treatment with RAPILYSIN.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

No other medicines should be added to the RAPILYSIN injection solution.

How RAPILYSIN is given

How much is given

The dosage of RAPILYSIN is expressed in units (U). These units only have meaning for RAPILYSIN and cannot be compared to units (U) that are used for other medicines.

One vial of RAPILYSIN contains 10 units (10 U) of reteplase. 10 U of reteplase corresponds to 17.4 mg of the drug.

During the normal course of treatment, you will be given 2 vials worth of RAPILYSIN (20 U or 34.8 mg of reteplase).

How it is given

RAPILYSIN is given as an injection into a vein over approximately 2 minutes, when your doctor believes that you have had a myocardial infarction (heart attack).

Because RAPILYSIN is short acting, you will receive a second injection approximately 30 minutes later.

RAPILYSIN is not normally given again, unless you have another myocardial infarction.

You may receive other medicines for your condition as well, such as aspirin and heparin. Heparin must not be combined with RAPILYSIN in the same injection.

Side effects

Tell your doctor or nurse immediately if you do not feel well while you are receiving RAPILYSIN.
RAPILYSIN generally causes few side effects and helps most people with myocardial infarctions. However, it may have unwanted side effects in a few people, or you may have a problem caused by your recent myocardial infarction (heart attack). Side effects or further problems may require additional treatment.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, pharmacist or nurse if you notice any of the following:

- bruising at the site of injection

- bleeding from the site of injection, or the gums, bowel or urine, or the eyes
- low blood pressure causing fainting or dizziness
- black-outs or loss of consciousness, numbness, inability to move parts of your body or difficulty speaking, confusion, abnormal thoughts, agitation, convulsions or fits. Bleeding into the brain is an uncommon serious side effect.
- irregular or racing heart beats
- nausea or vomiting
- fevers
- swelling, itching, shortness of breath, wheezing or cough. These can be signs of an allergic reaction.

These are some of the side effects of RAPILYSIN, though some of them may be caused by the myocardial infarction (heart attack) itself.

You may need urgent medical attention if some of these occur.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor, pharmacist or nurse if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor, pharmacist or nurse if you don't understand anything on this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After receiving RAPILYSIN

Storage

RAPILYSIN will be stored in the pharmacy or on the hospital ward, in refrigerator, on a shelf or in a cupboard at a temperature below 25°C. Do not freeze the entire pack.

Product description

Availability

RAPILYSIN comes in one strength, being 10 units (17.4 mg) per vial.

RAPILYSIN comes in a pack of 2 vials, with 2 reconstitution spikes, 2 syringes with solvent (liquid) in each syringe and 2 needles.

What RAPILYSIN looks like

RAPILYSIN is a white powder, which is dissolved in sterile water to make a clear, colourless solution.

Ingredients

Active ingredient - reteplase

- Each vial of RAPILYSIN powder contains 10 units (17.4 mg) reteplase

Inactive ingredients

- Each vial of RAPILYSIN powder also contains:
  - tranexamic acid
  - phosphoric acid
  - polysorbate 80
  - potassium phosphate, dibasic
  - sucrose
- Each syringe of solvent also contains:
  - water for injections

Sponsor

Actavis Pty Ltd
Level 5, 117 Harrington St
The Rocks NSW 2000

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number
AUST R 74138

This leaflet was prepared in November 2009.
Updated in April 2014