

Consumer Medicine Information

RAPILYSIN[®]

Retepase

10 U powder with solvent for solution for injection

What is in this leaflet

This leaflet answers some common questions about RAPILYSIN.

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 expected 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 belongs to a group of medicines called thrombolytics.

RAPILYSIN is used to treat myocardial infarctions (also called "heart attacks"). Heart attacks occur when the blood flow to part of the heart is blocked by a blood clot. The blockage causes part of the heart muscle to start to die.

RAPILYSIN works by dissolving the blood clot that is blocking the heart blood vessel.

If a heart attack is not treated quickly, it may lead to minor or severe heart damage and sometimes death. Because of this, RAPILYSIN should be given within 12 hours of the start of any heart attack symptoms. It only acts for a short period of time to dissolve blood clots.

RAPILYSIN is given together with other medicines that thin the blood such as heparin and acetylsalicylic acid (aspirin).

RAPILYSIN is related to a normal substance found in the blood.

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

You should not have RAPILYSIN if:

1. you have had an allergic reaction to RAPILYSIN, polysorbate 80, or any ingredients listed at the end of this leaflet
2. you have a tendency for bleeding, either easily caused or slow in stopping.
3. you are being treated with anticoagulant medicines (used to thin the blood and prevent blood clots) such as warfarin (Marevan[®], Coumadin[®]).
4. you have a growth, cancer or blood vessel problems within your head.
5. you have previously had a stroke.
6. you have had prolonged heart massage (also called CPR (cardiopulmonary resuscitation)) in the last 10 days.
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), which may cause ulceration and bleeding in your oesophagus (food pipe).
10. you have severe liver or kidney problems.
11. you have pancreatitis (sharp pain from the front of your stomach to the back)
12. you have inflammation of the area around your heart, or an infection affecting your heart.
13. you have any of the following in the last three months
 - severe bleeding
 - a major physical injury
 - major surgery
 - given birth
 - had part of a body organ removed for testing (biopsied)
 - had a needle in a major blood vessel
14. The package is torn or shows signs of tampering.
15. The expiry date printed on the pack has passed.
If you take this medicine after the expiry date has passed, it may not work as well.

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

RAPILYSIN is not recommended for children.

Safety and effectiveness of RAPILYSIN 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 except in life-threatening situations where the benefits of treatment outweigh the risk to the unborn baby.

2. you are breastfeeding

It is not known whether RAPILYSIN passes into breast milk. You should discard any breast milk for 24 hours after injection with RAPILYSIN.

3. you have any other health problems, especially the following:

- a stroke
- dizziness or blacking-out spells
- high blood pressure
- irregular heart beat
- problems with your heart valves
- any recent abnormal bleeding

4. you are older than 75 years of age

5. you are allergic to any other medicines, foods, dyes or preservatives

If you have not told your doctor about any of the above, do so before you are given 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:

- anticoagulation (blood thinning) medicines such as heparin (Monoparin[®], Multiparin[®], Prothrombinex-HT[®]), enoxaparin sodium (Clexane[®]), dalteparin sodium (Fragmin[®]), nadroparin calcium (Fraxiparine[®]), tinzaparin (Innohep[®]) and warfarin (Marevan[®], Coumadin[®])
- medicines that alter blood platelet function other than acetylsalicylic acid (aspirin, Aspro[®], Disprin[®], Aspec[®], Cartia[®], Cardiprin[®], Solprin[®]), such as dipyridamole (Persantin[®], Pytazen SR[®]) and abciximab (ReoPro[®]), ticlopidine, clopidogrel (Plavix[®]) or glycoprotein IIb/IIIa receptor antagonists (Integrilin[®], Aggrastat[®])

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.

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 or IU) that are used for other medicines.

One vial of RAPILYSIN contains 10 units (10U) of reteplase.

The usual course of treatment is 1 vial (10U) of RAPILYSIN, followed by another vial (10U) approximately 30 minutes later (a total of 2 vials or 20U).

How is it given

RAPILYSIN is given as an injection into a vein over approximately 2 minutes, when your doctor believes that you have had a heart attack. The second injection is given about 30 minutes later because RAPILYSIN is short acting.

RAPILYSIN is not normally given again, unless you have another heart attack.

You may receive other medicines for your condition as well, such as aspirin and heparin.

Side Effects

Tell your doctor or nurse immediately if you do not feel well while you are receiving RAPILYSIN.

RAPILYSIN helps most people with heart attacks. However, it may have unwanted side effects in a few people, or you may have a problem caused by your recent heart attack. Side effects or further problems may require additional treatment.

If you are over 75 years of age you may have an increased chance of getting side effects.

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

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

- bleeding from the site of the injection, or the gums, bowel or urine, or the eyes
- bruising at the site of injection, or elsewhere on your body
- burning or other reaction at the injection site
- you are coughing up blood
- nosebleed
- chest pain
- irregular or racing heart beat
- another heart attack occurring
- an allergic reaction occurring – symptoms of an allergic reaction include swelling, itching and/or shortness of breath
- feeling that you may black-out or lose consciousness
- feeling faint or dizzy, possibly caused by low blood pressure
- numbness, inability to move parts of your body or difficulty speaking
- confusion, abnormal thoughts, agitation
- convulsions or fits

These are some of the side effects of RAPILYSIN, although some of them may be caused by the 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 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 below 30°C, and protected from light. When made into solution, the injection should be used immediately.

RAPILYSIN must not be used after the expiry date stated on the carton and on the label of the vial.

Product Description

Availability

RAPILYSIN comes in one strength, 10U (17.4mg) reteplase per vial.

Each RAPILYSIN pack contains 2 vials, 2 reconstitution spikes, two syringes with solvent (water for injection) in each syringe and two 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

Each vial of RAPILYSIN powder contains 10U (17.4mg) of reteplase.

Inactive ingredients

Each vial of RAPILYSIN powder also contains tranexamic acid, phosphoric acid, polysorbate 80, dipotassium hydrogen phosphate, sucrose.

Distributor

RAPILYSIN is distributed by:

Pharmacy Retailing NZ Ltd trading as Healthcare Logistics

58 Richard Pearse Drive

Airport Oaks AUCKLAND

Phone No: 0508 555 100

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