GB-IE - 37018A

ReoPro®

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ReoPro®

Package leaflet: Information for the user

ReoPro® 2 mg/mL solution for injection or infusion

abciximab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor.
- If you get any of side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. **What ReoPro is and what it is used for**
2. **What you need to know before you are given ReoPro**
3. **How to use ReoPro**
4. **Possible side effects**
5. **How to store ReoPro**
6. **Contents of the pack and other information**

1. What ReoPro is and what it is used for

What ReoPro is?

The active ingredient, abciximab, is a 'murine monoclonal antibody'. Monoclonal antibodies are proteins that recognise and bind to other unique proteins. ReoPro belongs to a group of medicines known as antithrombotics and binds to proteins in your blood to help to prevent blood clots.

What is ReoPro used for?

ReoPro is used when you undergo an operation known as angioplasty (see "What is an angioplasty operation?" below) for the following purposes:

- ReoPro is used (together with heparin and acetylsalicylic acid) to prevent the formation of blood clots in the heart during or after an angioplasty operation.
- ReoPro is also used (together with heparin and acetylsalicylic acid) to lower the short term risk of getting a heart attack before an angioplasty operation, which is planned to take place within the next 1-month. This is for patients who have chest pain due to low blood supply to the heart (unstable angina) and have not responded to the usual therapy.

What is an angioplasty operation?

An angioplasty operation aims to open blocked arteries around the heart. A doctor will carefully guide a special instrument through an artery (which is usually in the groin) to reduce or remove the blockage.

There are three types of angioplasty operations where ReoPro can be used:
- Using an inflatable balloon to compress an artery blockage (balloon angioplasty)
- Using a cutting device to open a blocked artery (atherectomy)
- Inserting an expandable metal sheath to keep an artery open (stent)

2. What you need to know before you are given ReoPro

Do not use ReoPro

Your doctor will review your medical history to see if you are at an increased risk for any side effects associated with being given ReoPro.

To prevent risks of increased bleeding ReoPro must not be given:
- if you have internal bleeding
- if you have had a stroke within the last two years
- if you have had any head, spinal surgery (or trauma) or other major surgery in the last two months
- if you have brain cancer
- if you have serious bleeding problems or have very low amounts of platelets in your blood
- if you have uncontrolled high blood pressure
- if you have an abnormal bulge in one of your blood vessels (aneurysm)
- if you have serious problems with your liver
- if you are on dialysis for kidney failure

ReoPro must not be given if you are allergic (hypersensitive):
- to abciximab, to any of the other ingredients of ReoPro or to a group of medicines known as 'murine monoclonal antibodies'.
- to a protein called papain (or to papaya fruit which contains papain). Papain is used in the production of ReoPro and very small amounts may be present.

If you think that you fit into any of the categories described above, it is important that you discuss it with your doctor. ReoPro must not be given in these situations.

Warnings and precautions

Talk to your doctor before using ReoPro
- if you are taking blood-thinning medicines or any other medicines that affect blood clotting or blood platelets (see "Using other medicines" section).
- if you have previously received ReoPro, since this could be associated with higher risk of reduction in blood platelets or allergic reactions (hypersensitivity).
- if you have serious problems with your kidneys, since this may put you at risk of increased bleeding. In this case, your doctor might monitor your blood frequently.
- if you are more than 65 years of age (see "Adults over 65 years of age" section).

If you think that you fit into any of the categories described above, it is important that you discuss it with your doctor.

Adults over 65 years of age

In patients who are over 65 years of age, ReoPro should be given with caution, because of risks of increased bleeding.

Other medicines and ReoPro

Tell your doctor if you have been given blood-thinning medicines, or any other medicines that affect blood clotting ('anticoagulants') or blood platelets ('anti-platelet medicines'). It is particularly important that you tell your doctor if 'thrombolytic' medicines have been given to unblock your arteries. Being given ReoPro together with these medicines may put you at risk of increased bleeding.

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

ReoPro should not be given during pregnancy unless clearly necessary, since the effect of ReoPro on pregnant women or unborn children is not known.

Breast-feeding must be stopped before being given ReoPro, since it is not known whether ReoPro is secreted in breast milk.

3. How to use ReoPro

Your nurse or doctor will inject ReoPro liquid from a syringe into one of your veins. This is known as a 'bolus injection'.
After you have had the injection, your nurse, doctor or pharmacist will put more diluted ReoPro liquid into a bag which is connected by a tube to a needle which goes into one of your veins. This is known as a 'drip' or 'infusion'.

Depending on your condition ReoPro will be given to you as follows:
- If you are about to undergo an angioplasty operation, your doctor will give you the bolus injection 10 to 60 minutes before the operation begins. After the bolus injection your doctor will start the infusion. The infusion will continue for 12 hours after the operation is completed.

turn over

The following information is intended for healthcare professionals only:

Instructions for use and handling

1. Calculate the number of ReoPro vials needed. The recommended dose of ReoPro is a 0.25 mg/kg intravenous bolus immediately followed by a 0.125 µg/kg/min (to a maximum of 10 µg/min) continuous intravenous infusion.
2. Parenteral medicinal products should be inspected visually for particulate matter prior to administration. Preparations of ReoPro containing visibly opaque particles should NOT be used.
3. As with all parenteral medicinal products, aseptic procedures should be used during the administration of ReoPro.
4. Preparation of Bolus Injection: Withdraw the necessary amount of ReoPro for the bolus injection into a syringe. Filter the bolus injection using a sterile non-pyrogenic, low protein binding 0.2 / 0.22 µm or 5.0 µm syringe filter. The bolus should be administered over one (1) minute.
5. Preparation of intravenous infusion: Withdraw the necessary amount of ReoPro for the continuous infusion into a syringe. Inject into an appropriate container of sterile sodium chloride 9 mg/ml (0.9%) solution for injection or 5% glucose solution and infuse at the calculated rate via a continuous infusion pump. The continuous infusion should be filtered either upon admixture using a sterile, non-pyrogenic low protein binding 0.2 / 0.22 µm or 5.0 µm syringe filter or upon administration using an in-line, sterile, non-pyrogenic, low protein-binding 0.2 µm or 0.22 µm filter. Discard the unused portion at the end of the infusion period.
6. No incompatibilities have been shown with intravenous infusion fluids or commonly used cardiovascular medicinal products. Nevertheless, it is recommended that ReoPro be administered in a separate intravenous line whenever possible and not mixed with other medicinal products.
7. No incompatibilities have been observed with glass bottles or polyvinyl chloride bags or administration sets.
8. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

- If you have unstable angina (chest pain due to low blood supply to the heart) and are scheduled for an angioplasty operation, your doctor will give you the bolus injection up to 24 hours before the scheduled operation. After the bolus injection your doctor will start the infusion. The infusion will continue for 12 hours after the operation is completed.

Dosage

Your doctor will calculate the dose of ReoPro to give to you as follows:
- The dose of the bolus injection will be based on your body weight. The dose is 0.25 milligrams for every kilogram of your body weight.
- The infusion dose will also be based on your body weight. The dose is 0.125 micrograms per kilogram per minute up to a maximum of 10 micrograms per minute.

After the operation

After the angioplasty operation your doctor or nurse will gently press a dressing on the artery to stop any bleeding. Total bed rest is required by the patient and the leg on which the angioplasty has been performed must be kept in a straight position for at least 6 to 8 hours. You will also be carefully observed by your doctor and nurse and your blood pressure and pulse will be measured several times. Regular blood tests will also be performed to monitor your blood cell count.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Cases of fatal bleeding have been rarely reported.

Please tell your doctor immediately if you notice any of the following side effects, as your doctor will need to take immediate action and discontinue your treatment:

Common (affecting less than 1 person in 10):
- Bleeding in the stomach or intestines. Symptoms may include vomiting blood, blood in faeces or black faeces.

Uncommon (affecting less than 1 person in 100):
- Bleeding in the skull. Symptoms may include pain in the head; speech, visual or hearing difficulties; numbness or lack of feeling; problems with movement or balance.
- Rare (affecting less than 1 person in 1,000):Allergic reactions (including hypersensitivity and anaphylactic reactions). Symptoms may include skin rash; itchy and swollen skin; difficulty in breathing, dizziness.
- Build up of blood around the heart. Symptoms may include rapid heartbeat, chest pain, shortness of breath, sweating or fatigue.
- Serious restriction in breathing capacity. Symptoms may include shortness of breath, rapid and shallow breathing.
- Bleedings in the lungs. Symptoms may include coughing blood, wheezing, rapid breathing, airway obstruction.

Please also tell your doctor if you notice any of the following side effects:

Common (affecting less than 1 person in 10):
- Low blood platelet count. Symptoms may include easy or excessive bruising, bleeding under the skin, bleeding from nose or gums.
- Headache
- Slow heart rate
- Bleeding (may include bruising, purple skin rash, nose bleed, vaginal bleeding, blood in urine or faeces)
- Swelling of arms and legs
- Nausea or vomiting
- Back pain
- Chest pain
- Fever
- Pain at the injection site
- Pain in the abdomen

Rare (affecting less than 1 person in 1,000):
- Very low blood pressure. Symptoms include dizziness or feeling faint.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

In the UK, you can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

In Ireland, you can also report side effects directly via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, E-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ReoPro

Your doctor or other healthcare professionals will take care of handling and storing ReoPro according to the following instructions:
- Keep this medicine out of the reach and sight of children.
- Store in a refrigerator (2°C - 8°C).
- Do not freeze.
- Do not shake.
- Do not use this medicine after the expiry date which is stated on the carton and vial label after the letters EXP. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice discolouring of the liquid or opaque particles in the liquid.

6. Contents of the pack and other information

What ReoPro contains

- ReoPro 2 mg/mL is supplied as a solution for injection or infusion containing 10 milligrams of abciximab (active ingredient) dissolved in 5 millilitres of water for injection.
- The other ingredients are disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate, sodium chloride and polysorbate 80.

What ReoPro looks like and contents of the pack

- ReoPro 2 mg/mL pack contains a labelled glass vial filled with colourless and clear ReoPro liquid.

Marketing Authorisation Holder and Manufacturer
Janssen Biologics B.V.
Einsteinweg 101
2333 CB Leiden
The Netherlands.

For any additional information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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