REOPRO®

abciximab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about REOPRO. It does not contain all the available information. It does not take the place of talking with your doctor or nurse.

All medicines have risks and benefits.

Your doctor has weighed the risks of you being given REOPRO against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or nurse.

Keep this leaflet.
You may need to read it again.

What REOPRO is used for

REOPRO belongs to a class of medicines called antithrombotics which help to prevent blood clots.

REOPRO inhibits the aggregation of blood-clotting cells (called platelets) in the blood.

REOPRO is used in patients with heart disease caused by poor blood flow in the arteries of the heart (known as ischaemic cardiac complications).

REOPRO prevents the formation of blood clots in the heart that may occur during procedures to open blocked arteries in the heart (known as percutaneous coronary intervention). Examples of percutaneous coronary intervention procedures include balloon angioplasty, atherectomy and stent placement.

REOPRO is also used in patients who have severe chest pain with heart disease (known as unstable angina), when percutaneous coronary intervention is planned. REOPRO may be started 18 to 24 hours prior to the planned intervention.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

Before you have REOPRO

When you must not have it

Do not have REOPRO if you have an allergy to:

- any medicine containing abciximab
- any of the ingredients listed at the end of this leaflet
- specific disease-fighting protein substances (called murine proteins).

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not have this medicine if you have active internal bleeding.

Do not have this medicine if you have had gastrointestinal (GI) or genitourinary bleeding in the last 6 weeks.

Do not have this medicine if you have experienced trauma to your head or spine within the last two years.

Do not have this medicine if you have had major surgery or trauma in the last 6 weeks.

Do not have this medicine if you have severe high blood pressure, a history of stroke or problems with your blood including bleeding easily or low blood platelet count (known as thrombocytopenia).

Do not have this medicine if you have had a growth or cancer of the brain or problems with blood vessels in the brain; blood vessel inflammation (known as vasculitis).

Do not have this medicine if you have been given intravenous dextran before your procedure.

Do not have this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start having this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell

him/her before you are given REOPRO.

Taking other medicines

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

Some medicines may be affected by REOPRO or may affect how it works. These include:

- medicines which thin your blood (known as anti-coagulants) particularly if used within the past seven days
- medicines which stop platelets sticking together (known as anti-platelet medicines). This includes medicines which contain the active ingredients dipyridamole or ticlopidine
- medicines used to treat arthritis (known as non-steroidal anti-inflammatory medicines)
- medicines used to dissolve blood clots (known as thrombolytics).

These medicines may be affected by REOPRO or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while having this medicine.

How REOPRO is given

How much you will be given

Your doctor will decide the dosage of REOPRO to be given to you. This will depend on your body weight.

In patients undergoing percutaneous coronary intervention, the recommended starting dose is a rapid intravenous injection of 0.25 mg for every kilogram of body weight immediately followed by a 0.125 mcg/kg/min continuous intravenous infusion.

In patients with unstable angina for whom percutaneous coronary intervention is planned, the recommended initial dose is 0.25 mg for every kilogram of body weight. This will be followed by an infusion of 10 mcg/min, commencing 18 to 24 hours before the planned intervention and ceasing one hour after completion of the intervention.

How it will be given

REOPRO is a solution, which is injected directly into the vein (known as an intravenous injection). However, before you are injected with REOPRO, your doctor may give you other medicines such as aspirin and heparin.

Your doctor or nurse will inject REOPRO for you.

Never inject REOPRO yourself. Always let your doctor or nurse do this.

If you are given too much (overdose)

As you will have REOPRO under the supervision of your doctor, it is unlikely that you will have too much.

There has been no experience of overdosage using REOPRO. However, REOPRO may increase the risk of bleeding under such circumstances. A blood transfusion may restore platelet function.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are having REOPRO.

REOPRO may have unwanted side effects in a few people. All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

Tell your doctor or nurse if you notice any of the following and they worry you:

- nausea, vomiting
- back pain
- headache.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- pain where the needle went into your vein or pain along the vein following injection
- feeling faint (due to low blood pressure).

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor or nurse immediately:

- any signs of allergy (anaphylactic reaction) including:
  - rash, itching or hives on the skin
  - swelling of the face, lips, tongue or other part of the body
  - shortness of breath, wheezing or trouble breathing
- bleeding or bruising more easily than normal
- coughing up of blood and/or shortness of breath (from bleeding into the lungs)
- chest pain, irregular heartbeat (known as palpitations)
- bleeding (usually at the site in the groin or arm where the angioplasty tube was inserted).

The above list includes very serious side effects. You may need urgent medical attention.

Tell your doctor or nurse if you notice anything that is making you feel unwell.

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

After having REOPRO

Storage

This medicine will be stored in the hospital pharmacy or on the ward.

It will be kept in a cool dry place where the temperature stays between 2°- 8°C.

Product Description

What it looks like

REOPRO is a clear colourless solution.

Each pack of REOPRO contains one 5 mL vial

Ingredients

Each mL of REOPRO contains 2 mg of abciximab rmc, the active ingredient. It also contains:

- dibasic sodium phosphate dihydrate
- monobasic sodium phosphate (monohydrate)
- sodium chloride
- polysorbate 80
- water for injections.

Supplier

REOPRO is distributed by:

JANSSEN-CILAG Pty Ltd
1-5 Khartoum Road
Macquarie Park NSW 2113
Australia
Telephone: 1800 226 334

NZ Office: Auckland New Zealand
Telephone: 0800 800 806

Australian Registration Number:

The Australian Registration Number for REOPRO 10 mg/5mL vial is
AUST R 48864.

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