

PART III: CONSUMER INFORMATION

Pr **ReoPro**[®]
abciximab

Solution for Intravenous Injection

This leaflet is part III of a three-part "Product Monograph" published when ReoPro[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ReoPro[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is 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 aspirin) to prevent the formation of blood clots in the heart during or after an angioplasty operation.
- ReoPro[®] is also used (together with heparin and aspirin) 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).

What it does:

The active ingredient, abciximab, is a 'fragment of murine/human chimeric monoclonal antibody'. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. ReoPro[®] belongs to a group of medicines known as antithrombotics and binds to platelets in your blood to help to prevent blood clots.

When it should not be used:

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 bleeding in the intestines. Symptoms may include vomiting blood, blood in feces or black feces,
- 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.

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'.

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.

What the medicinal ingredient is:

abciximab

What the important nonmedicinal ingredients are:

Sodium phosphate, sodium chloride, polysorbate 80. No preservatives are added.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:

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 milliliters of water for injection.

What ReoPro[®] looks like and contents of the pack

ReoPro[®] 2 mg / mL pack contains a 5 mL labeled glass vial filled with colourless and clear ReoPro[®] liquid.

The vial stopper is free of natural rubber latex.

WARNINGS AND PRECAUTIONS

ReoPro[®] may increase the risk of bleeding, particularly if you are receiving other drugs to prevent your blood from clotting (blood thinners). Cases of death due to bleeding have been reported with the use of ReoPro[®].

BEFORE you use ReoPro[®] talk to your doctor or pharmacist:

- if you are taking blood-thinning medicines or any other medicines that affect blood clotting or blood platelets (see “INTERACTIONS WITH THIS MEDICATION” 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 are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.
- If you think that you fit into any of the categories described above, it is important that you discuss it with your doctor.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with ReoPro[®] include: 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.

PROPER USE OF THIS MEDICATION**Usual dose:**

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.

- 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.

Overdose:

There has been no experience with ReoPro[®] in human trials.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ReoPro[®] can cause side effects, although not everybody gets them. If you notice any of the below side effects, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist	
		Only if severe	In all cases
Common	Bleeding (including bruising, purple skin rash, nose bleed, vaginal bleeding, blood in urine and feces)		√
	Low blood platelet count. Symptoms include easy or excessive bruising, bleeding under the skin, bleeding from nose or gums.		√
	Chest pain		√
	Pain in the abdomen		√
	Slow heart rate		√
	Nausea or vomiting		√
	Pain at the injection site	√	
	Back pain	√	
	Headache	√	
	Swelling of arms and legs		√
	Very low blood pressure. Symptoms include dizziness or feeling faint		√
Uncommon	Bleeding in the skull. Symptoms include pain in the head; speech, visual or hearing difficulties; numbness or lack of feeling; problems with movement or balance		√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	
	Only if severe	In all cases
Build up of blood around the heart. Symptoms are a combination of rapid heartbeat, chest pain, shortness of breath, sweating and fatigue.		√
Bleeding in the lungs. Symptoms include coughing blood, wheezing, rapid breathing, airway obstruction.		√
Serious restriction in breathing capacity. Symptoms include shortness of breath, rapid and shallow breathing.		√
Bleeding in the intestines. Symptoms include vomiting blood, blood in faeces or black faeces.		√
Allergic reactions. Symptoms include skin rash, itchy and swollen skin, difficulty in breathing		√
Fatal bleeding		√

This is not a complete list of side effects. For any unexpected effects while taking ReoPro[®], contact your doctor or pharmacist.

HOW TO STORE IT

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Your doctor or other healthcare professionals will take care of handling and storing ReoPro[®] according to the following instructions:

- Keep out of the reach and sight of children.
- Store in a refrigerator (2°C and 8°C).
- Do not freeze.
- Do not shake.
- Do not use ReoPro[®] 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 ReoPro[®] if you notice discolouring of the liquid or opaque particles in the liquid.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect[®] Canada Web site at www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full Product Monograph go to www.janssen.com/canada or contact the manufacturer, Janssen Inc. at: 1-800-567-3331 or 1-800-387-8781

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