

Consumer Medicine Information

WARNING FOR CANCER PATIENTS: use of medicines like Novicrit that stimulate red blood cell production during chemotherapy has been associated with increased risk of death in some studies. Your doctor should only use Novicrit to treat your anaemia if it is caused by chemotherapy and blood transfusions are not an appropriate treatment option.

What is in this leaflet

This leaflet answers some common questions about Novicrit.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.sandoz.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Novicrit 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 Novicrit is used for

Novicrit is used:

- to treat anaemia associated with kidney disease
- to treat anaemia in patients receiving chemotherapy for certain types of cancer
- in patients with anaemia who are about to undergo surgery as an alternative to a blood transfusion where there is the likelihood of moderate blood loss
- in patients with anaemia who face major elective surgery and who, prior to it, donate blood so that their own blood can be given to them during and after surgery. Novicrit stimulates the production of red blood cells and hence, a higher volume of blood can be taken from these patients.

Novicrit contains the active ingredient epoetin lambda (rch). Epoetin lambda (rch) is man-made and works in exactly the same way as the natural hormone produced in your kidneys.

Epoetin lambda is a hormone which works by stimulating the production of red blood cells. It is used to treat anaemia, a condition in which there is a decreased number of red blood cells.

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.

Novicrit is available only with a doctor's prescription and is not addictive.

Before you use Novicrit

When you must not use it

Do not use Novicrit if you have an allergy to:

- epoetin lambda (rch), the active ingredient in Novicrit
- any of the other ingredients listed at the end of this leaflet
- any other similar medicines such as other erythropoietins
- any medicines that are manufactured using mammalian cells.

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 use this medicine if:

- you have or have had high blood pressure which is not properly controlled
- you have a medical condition where the production of red blood cells is reduced or stopped (Pure Red Cell Aplasia) which developed following treatment with any erythropoietin
- you are due to have surgery and for any reason cannot receive medication to reduce the risk of abnormal blood clotting
- you are due to have elective surgery and you do not donate your own blood before surgery and you have severe disorders of the veins and arteries.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to use it

Tell your doctor if you have or have had any of the following medical conditions:

- high blood pressure
- heart disease
- disorders of blood circulation resulting in pins and needles or cold hands and feet or muscle cramps in the legs
- cancer
- seizures
- gout
- porphyria, a rare blood pigment disorder
- chronic liver disease
- blood clots in the legs or lungs
- stroke or transient ischaemic attack (TIA).
- an allergy to latex

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding.

It is not known whether Novicrit passes into breast milk and could affect your baby.

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

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of the above, tell him/her before you start using Novicrit.

Taking other medicines

Tell your doctor or pharmacist 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 and Novicrit may interfere with each other. These include:

- iron supplements
- cyclosporin, an immunosuppressant.

Such medicines may be affected by Novicrit 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 taking this medicine.

How to use Novicrit

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

Your doctor will conduct investigations, for example blood tests, to help decide whether it is necessary for you to have Novicrit. They will work out the correct dose of Novicrit for you to use, how long the treatment should continue and how it will be given. This decision will be influenced by the cause of your anaemia. The dose you receive is based on your body weight in kilograms.

Novicrit is administered either into a vein (intravenously) or under the skin (subcutaneously). Your doctor will know which route of administration is preferable in your case.

How much to use

- In patients with kidney failure Novicrit will usually be administered by the intravenous route but may also be given by the subcutaneous route. The recommended initial dose is 50IU/kg bodyweight 3 times a week. The starting dose may be adjusted by your doctor as needed to properly control your condition.
- The initial dose for cancer patients is 150IU/kg bodyweight given subcutaneously 3 times a week. The starting dose may be adjusted by your doctor depending on how your anaemia responds to treatment.

- In patients who are scheduled for elective surgery, the subcutaneous route is used. The usual dose is 600IU/kg bodyweight for 3 weeks prior to surgery and on the day of surgery. Alternatively, 300 IU/kg may be administered for 10 consecutive days prior to surgery, on the day of surgery and for 4 days immediately after.
- In patients who donate blood prior to major surgery the recommended dose is 300IU to 600IU/kg bodyweight twice a week for 3 weeks. The intravenous route is used.

Iron is an important constituent of red blood cells. It is important that levels of iron in your blood are normal throughout Epoetin lambda treatment. Where appropriate you will receive iron tablets or injections to ensure that the iron in your body will not be used up as more red blood cells are produced.

How to inject Novicrit yourself

At the start of your therapy, Novicrit may be injected by medical staff. However, your doctor may decide that it is right for you to learn how to inject it under the skin yourself. You will receive appropriate training for you to do this.

Under no circumstances should you attempt to inject yourself before you have been trained to do so.

The Novicrit pre-filled syringe is ready for use. Only use solutions which are clear, colourless and free of visible particles.

Do not shake the syringes.

Ask your doctor if you are unsure of the correct dose for you.

They will tell you exactly how much to use.

Follow the instructions they give you.

If you inject the wrong dose, Epoetin lambda may not work as well and your problem may not improve.

Instructions on how to inject yourself

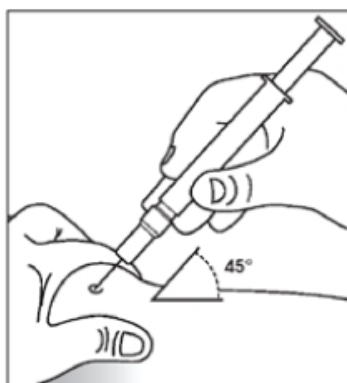
For patients with symptomatic anaemia caused by kidney disease, for adult patients receiving chemotherapy, adult patients scheduled for orthopaedic surgery, or adult patients with myelodysplastic syndromes only).

This section contains information on how to give yourself an injection of Novicrit. **It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse.** Novicrit is provided with or without a needle safety guard and you will be shown how to use this by your doctor or nurse. If you are not sure about giving the injection or you have any questions, please ask your doctor or nurse for help.

1. Wash your hands.
2. Remove one syringe from the pack and remove the protective cap from the injection needle. Syringes are embossed with graduation rings in order to enable partial use if required. Each graduation ring corresponds to a volume of 0.1 mL. If partial use of a syringe is required, remove unwanted solution before injection.
3. Clean the skin at the injection site using an alcohol wipe.
4. Form a skin fold by pinching the skin between thumb and forefinger.

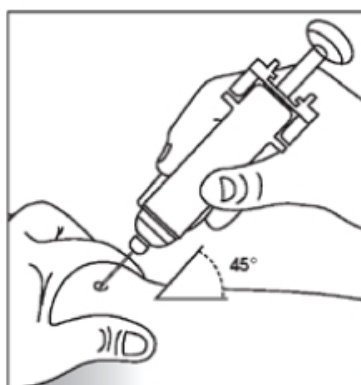
5. Insert the needle into the skin fold with a quick, firm action. Inject the Novicrit solution as you have been shown by your doctor. You should check with your doctor or pharmacist if you are not sure.

Pre-filled syringe without needle safety guard



6. Always keeping your skin pinched, depress the plunger slowly and evenly.
7. After injecting the liquid, remove the needle and let go of your skin. Apply pressure over the injection site with a dry, sterile pad.
8. Discard any unused product or waste material. Only use each syringe for one injection.

Pre-filled syringe with needle safety guard



6. Always keeping your skin pinched, depress the plunger slowly and evenly until the entire dose has been given and the plunger cannot be depressed any further. Do not release the pressure on the plunger!
7. After injecting the liquid, remove the needle while maintaining pressure on the plunger and then let go of your skin. Apply pressure over the injection site with a dry, sterile pad.
8. Let go of the plunger. The needle safety guard will rapidly move to cover the needle.
9. Discard any unused product or waste material. Only use each syringe for one injection.

How long to use it

Do not stop using this medicine without first checking with your doctor.

Your doctor will determine when your treatment should be stopped.

If you forget to use it

Inject your dose as soon as you remember, and continue to use it as you would normally.

If it is almost time for your next dose, skip the dose you missed and administer your next dose when you are meant to.

Do not inject a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much Novicrit. Do this even if there are no signs of discomfort or poisoning.

While you are using Novicrit

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Novicrit.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Things you must not do

Do not use Novicrit to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

If you have kidney failure be careful driving or operating machinery until you know how Novicrit affects you.

If you feel dizzy when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Novicrit.

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 lists of side effects. You may not experience any of them.

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

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

- flu-like symptoms such as headache, fever, sore throat, chills, difficulty swallowing, runny nose and cough, sore red eyes, muscle and joint pain and weakness, dizziness, drowsiness
- mild skin rashes
- skin reactions such as redness or burning at the injection site
- nausea, diarrhoea or vomiting.

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

- symptoms of an allergic reaction such as 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
- skin rashes and accumulation of fluid under the skin of the eyelids (oedema), which may result from an allergic reaction.
- sudden onset of a tender/painful red skin rash starting on the trunk
- seizures, or epileptic fits
- raised blood pressure, which may require treatment with drugs or adjustment of the doses of drugs you already take for high blood pressure
- clotting of your blood in the haemodialysis system, or blockage of your fistula if you are on dialysis. there may be a need to increase your heparin dose during dialysis
- chest pain, breathlessness, painful swelling in the leg that may be symptoms of a blood clot (thrombosis)
- severe, sudden, stabbing migraine-like headaches
- paralysis or weakness of an arm, leg and one side of the face, numbness, difficulty speaking, impaired vision, loss of balance or coordination
- pain in the foot or calf
- sudden tiredness, severe dizziness and light-headedness or sudden shortness of breath. There have been rare reports of patients developing antibodies against erythropoietins resulting in a failure of red blood cell development. This condition is called antibody-mediated Pure Red Cell Aplasia (PRCA). If you develop PRCA your Novicrit therapy will be discontinued and your doctor will decide how best to treat your anaemia.

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

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

Other side effects not listed here or not yet known may happen in some people. Some of these side effects can only be found by laboratory testing.

After using Novicrit

Storage

Keep the syringes in the original container until it is time to use them.

Keep your medicine in a cool dry place where the temperature stays between 2 and 8°C. Do not freeze.

Novicrit may be removed from the refrigerator and stored at up to 25°C for one single period of up to 3 days.

Keep it where children cannot reach it.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Novicrit solution for injection is a clear, colourless solution, presented in a glass syringe. Each pack of Novicrit contains 6 syringes.

Ingredients

Novicrit syringes contain 1,000IU; 2,000IU; 3,000IU; 4,000IU; 5,000IU; 6,000IU; 8,000IU or 10,000IU epoetin lambda (rch) as the active ingredient.

They also contain:

- dibasic dihydrate sodium phosphate
- monobasic dihydrate sodium phosphate
- sodium chloride
- glycine
- polysorbate 80
- hydrochloric acid
- sodium hydroxide
- water for injections.

The needle cover of the pre-filled syringe contains a derivative of latex (FM27)

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Novicrit is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

®= Registered Trademark

This leaflet was revised in August 2022.

Australian Registration Numbers:

1,000IU/0.5mL: - AUST R 147847
2,000IU/1.0mL: - AUST R 147833
3,000IU/0.3mL: - AUST R 147849
4,000IU/0.4mL: - AUST R 147843
5,000IU/0.5mL: - AUST R 147859
6,000IU/0.6mL: - AUST R 147844
8,000IU/0.8mL: - AUST R 147837
10,000IU/1.0mL: - AUST R 147842