

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

### 1. Why am I using Novicrit?

Novicrit contains the active ingredient epoetin lambda (rch). Novicrit is used to treat anaemia associated with kidney disease, anaemia due to chemotherapy to treat cancer. Novicrit can also be used for patients with mild anaemia who need to donate their own blood before surgery or as alternative to blood transfusion for patients having major bone surgery where high risk of blood transfusion complications.

For more information, see Section [1. Why am I using Novicrit?](#) in the full CMI.

### 2. What should I know before I use Novicrit?

Do not use if you have ever had an allergic reaction to Novicrit or any of the ingredients listed at the end of the CMI. 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. Do not use if you have uncontrolled high blood pressure, been diagnosed with pure red cell aplasia, cannot have transfusions with your own blood, or have severe heart disease, disorders with your veins or arteries, or had a recent heart attack or stroke, or are a surgery patient who should not be given medicines to thin your blood.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Novicrit?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Novicrit and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Novicrit?

Your doctor will determine the correct dose of Novicrit. Novicrit is administered either into a vein (intravenously) or under the skin (subcutaneously).

More instructions can be found in Section [4. How do I use Novicrit?](#) in the full CMI.

### 5. What should I know while using Novicrit?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using Novicrit. If you are receiving dialysis treatment when you begin treatment with Novicrit, your dialysis regimen may need to be adjusted. Have regular blood tests and have blood pressure taken when required by your doctor.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>Do not use Novicrit for any other complaint unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>Be careful before you drive or use any machines or tools until you know how Novicrit affects you.</li><li>Novicrit may cause dizziness in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>Store Novicrit between 2°C and 8°C in the refrigerator. Do not freeze.</li><li>Novicrit may be removed from the refrigerator and stored at up to 25°C for one single period of up to 3 days.</li></ul>

For more information, see Section [5. What should I know while using Novicrit?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. If you notice any of the following, tell your doctor immediately as you may need urgent medical care: severe, sudden, stabbing migraine-like headaches. Seizures, confusion or epileptic fits. Raised blood pressure, clotting of your blood in the haemodialysis system, or blockage of your fistula if you are on dialysis. Chest pain, breathlessness, painful swelling in the leg. Signs of an allergic reaction like skin rashes, hives, shortness of breath, wheezing or difficulty breathing, swelling of the face or eyelids. Sudden tiredness, dizziness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

**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.

# Novicrit®

Active ingredient(s): *Epoetin lambda (rch)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Novicrit. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Novicrit.**

Where to find information in this leaflet:

- [1. Why am I using Novicrit?](#)
- [2. What should I know before I use Novicrit?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Novicrit?](#)
- [5. What should I know while using Novicrit?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using Novicrit?

**Novicrit contains the active ingredient epoetin lambda (rch).** Novicrit is a protein that stimulates bone marrow to produce more red blood cells. Red blood cells are responsible for carrying oxygen to all parts of your body. A decrease in the number of red blood cells can cause anaemia. Some symptoms of anaemia are tiredness, breathlessness when exercising, and feeling cold. Anaemia may have many causes, including decreased production of a hormone called erythropoietin by the kidneys due to kidney failure, or as a result of chemotherapy treatments for cancer. Novicrit is virtually identical to your body's erythropoietin, and has a similar effect to naturally occurring erythropoietin in your body.

**Novicrit is used to treat the anaemia associated with kidney disease. If you have kidney disease, your kidney may not produce enough erythropoietin (necessary for red blood cell production) and your doctor may wish to correct this by prescribing Novicrit. This medicine stimulates your bone marrow to produce more red blood cells, helping to treat your anaemia.**

Novicrit can also be used to treat anaemia if you are receiving chemotherapy for cancer and your doctor decides that a blood transfusion is not appropriate.

Doctors can also prescribe Novicrit for mildly anaemic patients who are going to have surgery and donate blood before surgery, so that their own blood can be given to them during or after surgery. Because Novicrit stimulates the production of red blood cells, a higher volume of blood can be taken from these patients.

**Novicrit can be used as an alternative to a blood transfusion in adult patients about to undergo major orthopaedic (bone) surgery where there is a potentially high risk from blood transfusion complications.**

**Novicrit is not addictive.**

**This medicine is available only with a doctor's prescription.**

### 2. What should I know before I use Novicrit?

#### Warnings

**Do not use Novicrit if:**

- you are allergic to epoetin lambda (rch), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- If you have high blood pressure that is not properly controlled with blood pressure-lowering drugs.
- If you are a surgery patient who should not be given medicines to thin the blood.
- If you are due to have elective surgery and you have severe heart disease, disorders of the veins or arteries, or have recently had a heart attack or stroke.
- If you have been diagnosed with Pure Red Cell Aplasia (your bone marrow cannot produce enough red blood cells) after previous treatment with an erythropoietin product, including Novicrit.
- If you cannot have transfusions with your own blood during or after surgery.
- Do not use Novicrit if the packaging is torn or shows signs of tampering.
- Do not use Novicrit beyond the expiry date (month and year) printed on the pack.
- **Do not misuse Novicrit.** Misuse by healthy people may lead to life-threatening problems with the heart and blood vessels (e.g., stroke, heart attack, or blood clots).

**Check with your doctor if you have or have had:**

- high blood pressure
- heart disease (such as angina)
- disorders of blood circulation resulting in pins and needles or cold hands or feet or muscle cramps in the legs.
- blood clotting disorders
- seizures or epileptic fits take any medicines for any other condition
- cancer. If you are a cancer patient be aware that erythropoietins like Novicrit may act as a growth

factor and therefore in theory may affect the progression of your cancer. Please discuss this with your doctor.

- anaemia from other causes
- liver disease
- gout
- porphyria (a rare blood pigment disorder)
- an allergy to latex.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

In many women with severe kidney failure, their monthly periods may stop. In these women, erythropoietin may restart the monthly cycle. Before starting Novicrit, you should discuss the need for contraception with your doctor.

Make sure you tell your doctor if you have any other medical problems since these may affect the use of Novicrit.

If you have used Novicrit or another erythropoietin in the past, and you lost the good response you were having, tell your doctor about this.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given Novicrit.

Your doctor will advise you whether or not to use Novicrit or if you need to adjust the dose or adapt your treatment.

## **3. What if I am taking other medicines?**

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

Iron is also a constituent of red blood cells. Therefore, iron supplements and other blood stimulating drugs may increase your response to Novicrit treatment. Your doctor will decide whether you should take other medicines while using Novicrit.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Novicrit.**

## **4. How do I use Novicrit?**

### **How much to use**

- Your doctor will determine the correct dose of Novicrit. Novicrit is administered either into a vein (intravenously) or just under the skin (subcutaneously). Your doctor can discuss with you

whether injection into the vein or under the skin is preferable.

- For patients with anaemia due to kidney failure, Novicrit should be given intravenously, (into a vein or a tube that goes into a vein) if intravenous access is routinely available (haemodialysis patients). For patients not yet on dialysis and those on peritoneal dialysis Novicrit can be administered subcutaneously. The usual starting dose is 50 IU/kg three times per week for adults and 25 IU/kg three times per week for children, after which the dose may be changed by your doctor as needed.
- For patients who are scheduled for surgery and who are not storing their own blood the usual dose is 300 IU/kg body weight for 10 days before surgery, on the day of surgery and for 4 days after. Alternatively a dose of 600 IU/kg may be administered weekly for 3 weeks before surgery and on the day of surgery. The subcutaneous route is used.
- For anaemic cancer patients receiving chemotherapy, the initial dose is 150 IU/kg three times per week. After 4 weeks your doctor will check your response and increase the dose to 300 IU/kg three times weekly if response has been insufficient. If at any stage Novicrit has produced too many red cells, your doctor will stop the drug and later re-start it at a lower dose. The subcutaneous route is used.

### **When to use Novicrit**

#### **Injecting Novicrit under the skin yourself**

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

**Under no circumstances should you attempt to inject yourself unless 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 Novicrit pre-filled 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.

### **How to inject Novicrit under the skin**

**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).**

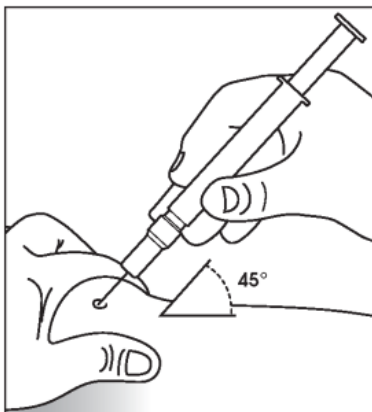
This section contains information on how to give yourself an injection of Novicrit. **It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse.** Novicrit is provided with or without a needle safety guard and you

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.

**WARNING:** Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap. Do not use the Novicrit prefilled syringe if it is broken. Return the prefilled syringe and the package it came in to the pharmacy.

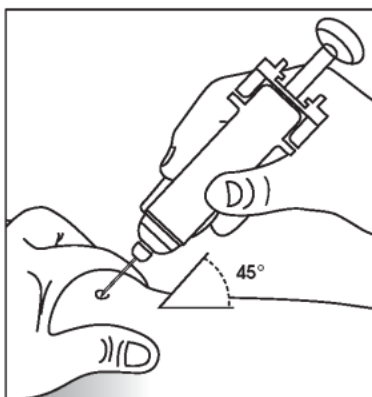
1. Wash your hands.
2. Remove one syringe from the pack and remove the protective cap from the injection needle. Syringes are embossed with graduation rings in order to enable partial use if required. Each graduation ring corresponds to a volume of 0.1 mL. If partial use of a syringe is required, remove 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.

#### If you forget to use Novicrit

Novicrit should be used regularly at the same time.

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

**Do not take a double dose to make up for the dose you missed.**

#### If you use too much Novicrit

If you think that you have used too much Novicrit, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Novicrit?

### Things you should do

- Always follow your doctor's instructions carefully.

If you are receiving dialysis treatment when you begin treatment with Novicrit, your dialysis regimen may need to be adjusted. Your doctor will decide this.

You will need to have regular blood tests while you are using Novicrit to see how you respond to treatment with Novicrit. Your doctor will order regular blood tests to ensure that your medicine is continuing to work properly. If your haemoglobin levels are above 120 g/L, discuss reducing your Novicrit dose with your doctor.

Your doctor will need to monitor your blood pressure regularly, especially at the beginning of treatment.

An increase in levels of small cells (called platelets) in your blood may occur, particularly when starting haemodialysis treatment.

- Tell your doctor if you become pregnant while using Novicrit.
- If you experience a severe skin reaction, a rash, which may be severe, may cover your whole body and can also include blisters or areas of skin coming off, stop

using Novicrit and call your doctor or get medical help right away.

- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are using Novicrit.
- If you become increasingly tired, dizzy or breathless, you should talk to your doctor at once. Your doctor can decide whether Novicrit is not working properly for you and will end the treatment if necessary.
- If you are due to have major surgery, your doctor will give you a medicine to reduce the risk of abnormal blood clotting.
- Remember to tell your doctor if you received Novicrit or another erythropoietin-like medicine in the past and you experienced a worsening in your anaemia.
- Take special care with other products that stimulate red blood cell production: Novicrit is one of a group of products that stimulate the production of red blood cells like the human protein erythropoietin does. If you are given a product in this group other than the one prescribed by your doctor during your treatment, speak to your doctor before using it. It is important that you continue to use the same product in the group unless your doctor says otherwise.

Remind any doctor, dentist or pharmacist you visit that you are using Novicrit.

### Things you should not do

- Do not use Novicrit to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Novicrit affects you.**

Novicrit may cause dizziness in some people

### Looking after your medicine

- **Keep the syringes in the original container until it is time to use them.**
- **Store Novicrit between 2°C and 8°C in the refrigerator. 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.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Nausea, vomiting or diarrhoea</li> <li>• Cough or congested airways such as stuffy nose and sore throat</li> <li>• Flu-like symptoms such as dizziness, drowsiness, fever, chills, headache, muscle and joint pain and weakness.</li> <li>• Redness, burning and pain at the site Novicrit is given.</li> <li>• Swelling of the lower legs or hands.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Severe, sudden, stabbing migraine-like headaches.</li> <li>• Seizures, confusion or epileptic fits.</li> <li>• Raised blood pressure, which may require treatment with drugs or adjustment of the doses of drugs you already take for high blood pressure.</li> <li>• 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.</li> <li>• Chest pain, breathlessness, painful swelling in the leg that may be symptoms of a blood clot (thrombosis).</li> <li>• Skin rashes and accumulation of fluid under the skin of the eyelids (oedema), which may result from an allergic reaction.</li> <li>• Signs of allergy such rash, itching or hives on the skin; shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<ul style="list-style-type: none"> <li>Sudden tiredness, dizziness or sudden shortness of breath.</li> </ul> <p>Your doctor will want to investigate this. These symptoms may be caused by a condition called pure red cell aplasia (PRCA). PRCA has been rarely reported after months to years of treatment with epoetin. PRCA means the absence of very young red blood cells in the bone marrow. If this condition develops, you suddenly lose the good response you have been having to Novicrit. As the previous cases of PRCA occurred mainly with subcutaneous administration it is preferable that Novicrit be administered intravenously whenever possible. Although PRCA is rare, you should be informed that if it develops, you would need to have regular blood transfusions to treat your anaemia, and Novicrit would have to be stopped.</p>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Novicrit contains

<b>Active ingredient (main ingredient)</b>	epoetin lambda (rch)
<b>Other ingredients (inactive ingredients)</b>	dibasic dihydrate sodium phosphate monobasic dihydrate sodium phosphate sodium chloride glycine polysorbate 80 hydrochloric acid

	sodium hydroxide water for injection
<b>Potential allergens</b>	The needle cover of the pre-filled syringe contains a derivative of latex (FM27)

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Novicrit looks like

Novicrit 1,000IU/0.5mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147847).

Novicrit 2,000IU/1.0mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147833).

Novicrit 3,000IU/0.3mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147849).

Novicrit 4,000IU/0.4mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147843).

Novicrit 5,000IU/0.5mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147859).

Novicrit 6,000IU/0.6mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147844).

Novicrit 7,000IU/0.7mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147835).

Novicrit 8,000IU/0.8mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147837).

Novicrit 9,000IU/0.9mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147838).

Novicrit 10,000IU/1.0mL - clear, colourless solution, presented in a glass syringe. Each pack contains 1 or 6 syringes (AUST R 147842).

*Not all presentations may be available in Australia.*

### Who distributes Novicrit

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

This leaflet was prepared in December 2025.

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