

BINOCRIT[®] PREFILLED SYRINGES

epoetin alfa (rch)

Consumer Medicine Information

WARNING FOR CANCER PATIENTS: use of medicines like Binocrit that stimulate red blood cell production during chemotherapy has been associated with increased risk of death in some studies. Your doctor should only use Binocrit 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 Binocrit prefilled syringes. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

It is important that you read this leaflet.

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

What Binocrit is used for

The prefilled syringes contain the active ingredient epoetin alfa, 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. This medicine is virtually identical to your body's erythropoietin, and has a similar effect to naturally occurring erythropoietin in your body.

This medicine is used to treat:

- 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 this medicine. This medicine stimulates your bone marrow to produce more red blood cells, helping to treat your anaemia.
- anaemia and reduce the need for a blood transfusion if you are receiving chemotherapy for cancer and your doctor decides you may need a blood transfusion.
- 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 this medicine stimulates the production of red blood cells, a higher volume of blood can be taken from these patients.
- adult patients about to undergo major orthopaedic (bone) surgery,

as an alternative to a blood transfusion, where there is a potentially high risk from blood transfusion complications.

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.

This medicine is not addictive.

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

Before you use Binocrit

When you must not take it

Do not use this medicine if you have an allergy to:

- epoetin alfa, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- 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 high blood pressure that is not properly controlled with blood pressure-lowering medication
- are a surgery patient who should not be given medicines to thin the blood
- are due to have elective surgery and have severe heart disease, disorders of the veins or arteries, or have recently had a heart attack or stroke
- 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 Binocrit
- if you cannot have transfusions with your own blood during or after surgery.

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 to use this medicine, talk to your doctor.

Before you start to take it

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

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

- 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
- cancer. If you are a cancer patient be aware that erythropoietins like this medicine, 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

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

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

In many women with severe kidney failure, their monthly periods may stop. In these women, erythropoietin may restart the monthly cycle. Before starting this medicine, 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 this medicine.

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

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

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

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 Binocrit may interfere with each other. These include:

- ciclosporin

- iron supplementation. Iron is also a constituent of red blood cells, therefore iron supplements and other blood stimulating medicines may increase your response to this medicine.

These medicines may be affected by Binocrit 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 you are given this medicine.

How to use Binocrit

Follow all directions given to you by your doctor or pharmacist 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.

How much to use

Your doctor will determine the correct dose of this medicine. The injection is administered either into a vein (intravenously) or just under the skin (subcutaneously). After instruction, you can administer it under the skin yourself if you wish. Your doctor can discuss with you whether injection into the vein or under the skin is preferable.

- In patients with anaemia due to kidney failure, Binocrit 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, Binocrit 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.

- In 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.
- In 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, this medicine 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.

Injecting Binocrit under the skin yourself

At the start of your therapy, this medicine may be injected by medical or nursing staff. However, your doctor may decide that it is right for you to learn how to inject this medicine 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.

If this medicine is injected under the skin (subcutaneously), the amount injected is not normally more than one millilitre (1 mL) in a single injection.

This medicine is given alone and not mixed with other liquids for injection.

Only use this medicine if the solution is clear, colourless and free of visible particles.

Do not shake Binocrit prefilled syringes.

Prolonged vigorous shaking may damage this medicine. If it has been shaken vigorously, don't use it.

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

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Binocrit 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 Binocrit. **It is important that you do not try to give yourself the injection unless you have received special training from your doctor or nurse.** Binocrit 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.

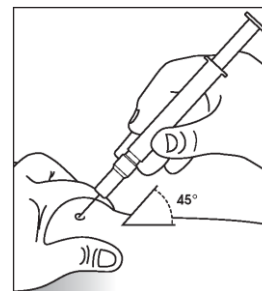
WARNING: Do not use if the syringe has been dropped onto a hard surface or dropped after removing the needle cap. Do not use the Binocrit prefilled syringe if it is broken. Return the prefilled syringe and the package it came in to the pharmacy.

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.

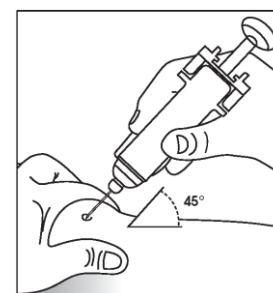
3. Clean the skin at the injection site using an alcohol wipe.
4. Form a skin fold by pinching the skin between thumb and forefinger.
5. Insert the needle into the skin fold with a quick, firm action. Inject the Binocrit solution as you have been shown by your doctor. You should check with your doctor 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

Only take one dose of Binocrit from each syringe. If any liquid remains in the syringe after an injection, the syringe should be properly disposed of and not reused. Binocrit prefilled syringes do not contain preservatives. Therefore, once a syringe has been opened, any remaining solution must be discarded.

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

If you forget to take it

Administer your dose as soon as you remember, and continue to take 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 administer 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 have missed more than one dose or are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when 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 Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Binocrit.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Binocrit

Things you must do

Always follow your doctor's instructions carefully.

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

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

If you are receiving dialysis treatment when you begin treatment with this medicine, your dialysis regimen may need to be adjusted.

Your doctor will decide this.

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

It may affect other medicines used during surgery. Your doctor will give you a medicine to reduce the risk of abnormal clotting.

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

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

It may interfere with the results of some tests.

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

Your doctor may do some tests (i.e. blood pressure, blood tests) regularly to make sure the medicine is working and to prevent unwanted side effects. If your haemoglobin levels are above 120 g/L, discuss reducing your Binocrit dose with your doctor.

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

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 Binocrit and call your doctor or get medical help right away.

If you become increasingly tired, dizzy or breathless, you should talk to your doctor at once.

Your doctor can decide whether this medicine is not working properly for you and will end the treatment if necessary.

Tell your doctor if you received Binocrit 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.

This medicine is one of a group of products that stimulate the production of red blood cells like the human protein erythropoietin dose. 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.

Things you must not do

Do not use Binocrit 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 Binocrit affects you.

This medicine may cause dizziness in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

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 use 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 using Binocrit.

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 if you experience any of the following and they worry you:

- flu-like symptoms such as dizziness, drowsiness, fever,

chills, headache, muscle and joint pain and weakness

- cough or congested airways such as stuffy nose and sore throat
- redness, burning and pain at the site this medicine is given
- nausea, diarrhoea and vomiting.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe, sudden, stabbing migraine-like headaches
- seizures, confusion or epileptic fits
- raised blood pressure, which may require treatment with medication or adjustment of the doses of medication 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)
- skin rashes and accumulation of fluid under the skin of the eyelids (oedema), which may result from an allergic reaction
- signs of allergy such as 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
- sudden tiredness, dizziness or sudden shortness of breath.

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 this medicine. 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 this medicine. Due to product improvements PRCA is now very rare but as the previous cases occurred mainly with subcutaneous administration, it is preferable that this medicine be administered intravenously wherever possible. Although PRCA is rare, you should be informed that if it develops, you will need to have regular blood transfusions to treat your anaemia and Binocrit would have to be stopped.

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

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

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

After using Binocrit

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Immediately prior to use, Binocrit may be stored in a room that stays below 25°C for a maximum single period of three days.

Do not store Binocrit or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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

Binocrit solution for injection is a clear, colourless solution, presented in a glass graduated syringe. Each pack of Binocrit contains 1 or 6 syringes.

Ingredients

Active ingredients:

- Binocrit 1,000 IU / 0.5 mL - 1,000IU epoetin alfa (rch)
- Binocrit 2,000 IU / 1.0 mL - 2,000IU epoetin alfa (rch)
- Binocrit 3,000 IU / 0.3 mL - 3,000IU epoetin alfa (rch)
- Binocrit 4,000 IU / 0.4 mL - 4,000IU epoetin alfa (rch)
- Binocrit 5,000 IU / 0.5 mL - 5,000IU epoetin alfa (rch)
- Binocrit 6,000 IU / 0.6 mL - 6,000IU epoetin alfa (rch)
- Binocrit 7,000 IU / 0.7 mL - 7,000IU epoetin alfa (rch)
- Binocrit 8,000 IU / 0.8 mL - 8,000IU epoetin alfa (rch)
- Binocrit 9,000 IU / 0.9 mL - 9,000IU epoetin alfa (rch)
- Binocrit 0,000 IU / 1.0 mL - 10,000IU epoetin alfa (rch)
- Binocrit 20,000 IU / 0.5 mL - 20,000IU epoetin alfa (rch)
- Binocrit 30,000 IU / 0.75 mL - 30,000IU epoetin alfa (rch)
- Binocrit 40,000 IU / 1.0 mL - 40,000IU epoetin alfa (rch)

Inactive ingredients:

- sodium dihydrogen-phosphate dihydrate

- disodium hydrogen-phosphate dihydrate
- sodium chloride
- glycine
- polysorbate 80
- nitrogen
- hydrochloric acid
- sodium hydroxide
- water for injections.

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

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

Supplier

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

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