

# BINOCRIT<sup>®</sup> PRE-FILLED SYRINGE

Epoetin alfa (2000IU/ml, 4000IU/0.4ml, 10 000IU/ml, 40 000IU/ml)

## What is in this leaflet

1. What BINOCRIT<sup>®</sup> is used for
2. How BINOCRIT<sup>®</sup> works
3. Before you use BINOCRIT<sup>®</sup>
4. How to use BINOCRIT<sup>®</sup>
5. While you are using BINOCRIT<sup>®</sup>
6. Side effects
7. Storage and disposal of BINOCRIT<sup>®</sup>
8. Product description
9. Manufacturer and product registration holder
10. Date of revision

## What BINOCRIT<sup>®</sup> is used for

BINOCRIT<sup>®</sup> is used to treat symptomatic anemia caused by kidney disease

- in children on hemodialysis
- in adults on hemodialysis, peritoneal dialysis or not yet undergoing dialysis.

If you have kidney disease, you may be short of red blood cells if your kidney does not produce enough erythropoietin (necessary for red cell production). BINOCRIT<sup>®</sup> is prescribed to stimulate your bone marrow to produce more red blood cells.

BINOCRIT<sup>®</sup> is used to treat anemia if you are receiving chemotherapy for solid tumors, malignant lymphoma or multiple myeloma (bone marrow cancer) and your doctor decides you may have a need for a blood transfusion. BINOCRIT<sup>®</sup> can reduce the need for a blood transfusion.

BINOCRIT<sup>®</sup> is used in moderately anemic people who donate some of their blood before surgery, so that it can be given back to them during or after the operation. Because BINOCRIT<sup>®</sup> stimulates the production of red blood cells, doctors can take more blood from these people.

BINOCRIT<sup>®</sup> is used in moderately anemic adults about to have major orthopedic surgery (for example hip or knee replacement operations), to reduce the potential need for blood transfusions.

BINOCRIT<sup>®</sup> is used to treat anemia in adults with low- or intermediate-1-risk myelodysplastic syndromes. BINOCRIT<sup>®</sup> can reduce the need for a blood transfusion.

## How BINOCRIT<sup>®</sup> works

BINOCRIT<sup>®</sup> contains the active substance epoetin alfa - a protein that stimulates the bone marrow to produce more red blood cells which carry hemoglobin (a substance that transports oxygen). Epoetin alfa is a copy of the human protein erythropoietin (ee-rith-roe-p-o-e-h-tin) and acts in the same way.

## Before you use BINOCRIT<sup>®</sup>

### - When you must not use it

Do not use BINOCRIT<sup>®</sup>:

- If you are allergic (hypersensitive) to Epoetin alfa or any of the other ingredients of BINOCRIT<sup>®</sup>
- If you have been diagnosed with Pure Red Cell Aplasia (the bone marrow cannot produce enough red blood cells) after previous treatment with any product that stimulates red blood cell production
- If you have high blood pressure not properly controlled with medicines.
- To stimulate the production of your red blood cells (so that doctors can take more blood from you) if you cannot have transfusions with your own blood during or after surgery
- Seizures
- If you are due to have major orthopedic surgery (such as hip or knee surgery), and you:
  - have severe heart disease
  - have severe disorders of the veins and arteries
  - have recently had a heart attack or stroke
  - can't take medicines to thin the blood. BINOCRIT<sup>®</sup> may not be suitable for you. Please discuss with your doctor. While on BINOCRIT<sup>®</sup>, some people need medicines to reduce the risk of blood clots. If you can't take medicines to prevent blood

clotting, you must not have BINOCRIT<sup>®</sup>.

BINOCRIT<sup>®</sup> should not be used:

- after the expiry date on the label and outer carton
- if you know, or think that it may have been accidentally frozen, or
- if there has been a refrigerator failure.

### - Before you start to use it

Take special care with BINOCRIT<sup>®</sup>.

- BINOCRIT<sup>®</sup> and other products that stimulate red cell production may increase the risk of developing blood clots in all patients. This risk may be higher if you have other risk factors for developing blood clots (for example, if you have had a blood clot in the past or are overweight, have diabetes, have heart disease or you are off your feet for a long time because of surgery or illness). Please tell your doctor about any of these things. Your doctor will help you to decide if BINOCRIT<sup>®</sup> is suitable for you.

It is important to tell your doctor if any of the following apply to you. You may still be able to use BINOCRIT<sup>®</sup> but discuss it with your doctor first.

- If you know you suffer, or have suffered, from:
  - high blood pressure
  - epileptic seizures or fits
  - liver disease
  - anemia from other causes • porphyria (a rare blood disorder)
  - an allergy to latex

- If you are a cancer patient, be aware that products that stimulate red blood cell production (like BINOCRIT<sup>®</sup>) may act as a growth factor and therefore in theory may affect the progression of your cancer. Depending on your individual situation a blood

transfusion may be preferable. Please discuss this with your doctor.

- If you are a cancer patient, be aware that use of BINOCRIT® may be associated with shorter survival and a higher death rate in head and neck, and metastatic breast cancer patients who are receiving chemotherapy.

- 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.

#### Pregnancy, breast-feeding and fertility

It is important to tell your doctor if any of the following apply to you. You may still be able to use BINOCRIT®, but discuss it with your doctor first.

- If you are pregnant, planning to become pregnant, or think you may be pregnant.
- If you are breast feeding, or are planning to breast-feed.

#### - Taking other medicines

BINOCRIT® does not normally react with other medicines but please tell your doctor if you are using (or have recently used) any other medicines – including medicines obtained without a prescription.

If you are taking a drug called cyclosporin (used e.g. after kidney transplants), your doctor may order blood tests to check the level of cyclosporin while you are taking BINOCRIT®.

Iron supplements and other blood stimulants may increase the effectiveness of BINOCRIT®. Your doctor will decide if it is right for you to take them.

If you visit a hospital, clinic or family doctor, tell them you are having BINOCRIT® treatment. It may affect other treatments or test results.

If you are a patient with hepatitis C and you receive interferon and ribavirin: You

should discuss this with your doctor because a combination of epoetin alfa with interferon and ribavirin has led to a loss of effect and development of a condition called pure red cell aplasia (PRCA), a severe form of anemia, in rare cases. BINOCRIT® is not approved in the management of anemia associated with hepatitis C.

If you have any further questions on the use of this product, ask your doctor, nurse or pharmacist.

#### **How to use BINOCRIT®**

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Your doctor has carried out blood tests and decided you need BINOCRIT®.

BINOCRIT® may be given by injection:

- Either into a vein or a tube that goes into a vein (intravenously)
  - BINOCRIT® should be administered over at least one to five minutes, depending on the total dose.
- Or under the skin (subcutaneously).

Your doctor will decide how BINOCRIT® will be injected. Usually the injections will be given to you by a doctor, nurse or other healthcare professional. Some people, depending on why they need BINOCRIT® treatment, may later learn how to inject themselves under the skin: see Instructions on how to inject BINOCRIT® yourself.

Instructions on how to inject BINOCRIT® 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

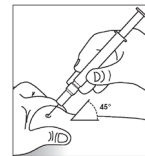
guard and you will be shown how to use this by your doctor or nurse. If you are not sure about giving the injection or you have any questions, please ask your doctor or nurse for help.

**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 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 0.1mL. If partial use of a syringe is required, remove unwanted solution before injection.
3. Clean the skin at the injection site using 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.

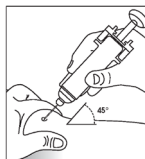
#### Pre-filled syringe without needle safety guard

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!
- 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.
  - Let go of the plunger. The needle safety guard will rapidly move to cover the needle.
  - Discard any unused product or waste material. Only use each syringe for one injection.

Instructions for injecting BINOCRIT® under the skin  
BINOCRIT® should not be shaken.

The amount injected in any one place should not normally exceed one millilitre (1 ml).

The injections are given preferably in the thigh or the front part of the abdominal wall.

At the start of your therapy, BINOCRIT® may be injected by medical staff. However, your doctor may decide that it is right for you to learn how to inject BINOCRIT® under the skin 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.**

- How much to use

The dose of BINOCRIT® you receive is based on your bodyweight in kilograms. The cause of your anemia is also a factor in your doctor deciding the correct dose.

Your doctor will monitor your blood pressure regularly while you are using BINOCRIT®.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking BINOCRIT® for as long as your doctor recommends.

- If you forget to use it

Make the next injection as soon as you remember. If you are within a day of your next injection, forget the missed one and carry on with your normal schedule. Do not double up the injections.

- If you use too much (overdose)

Tell the doctor or nurse immediately if you think too much BINOCRIT® has been injected. Side effects from an overdose of BINOCRIT® are unlikely.

**While you are using BINOCRIT®**

- Things you must do

Always follow your doctor's instructions carefully.

- Things you must not do

- Do not use BINOCRIT® 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.

- Things to be careful of

Take special care with other products that stimulate red blood cell production:

BINOCRIT® is one of a group of products that stimulate the production of red blood cells like the human protein erythropoietin does. Your healthcare professional will always record the exact product you are using.

If you are given a product in this group other than BINOCRIT® during your treatment, speak to your doctor or pharmacist before using it.

**Side Effects**

Like all medicines, BINOCRIT® can cause side effects, although not everybody gets them.

Tell your doctor or nurse immediately if you notice any of the effects in this list.

The most frequently occurring adverse reactions observed in clinical trials of epoetin alfa were:

- High blood pressure
- Diarrhea
- Nausea
- Vomiting

- Fever
- Headache
- Flu-like symptoms: more common at the start of treatment

Very rare side effects include:

- Erythropoietin antibody-mediated pure red cell aplasia
- Thrombocythaemia (increased of platelet cells in blood)

Tell your doctor or nurse immediately if you are aware of any of these effects, or if you notice any other effects while you are receiving treatment with BINOCRIT®.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI))).

**Storage and disposal of BINOCRIT®**

- Storage

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date, which is stated on the box and on the label after the letters EXP. The expiry date refers to the last day of that month.
- Store and transport refrigerated (2°C -8°C).
- Do not freeze.
- Keep the pre-filled syringe in the outer carton in order to protect from light.

Do not use BINOCRIT®

- If the solution is cloudy or there are particles in it
- If the seal is broken
- If the solution has been accidentally frozen

- Disposal

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

MAL20112124ACZ

**Product description**

- *What it looks like*

BINOCRIT® is presented as a clear, colourless solution for injection in a pre-filled syringe. The syringes are sealed in a blister.

Binocrit 2,000 IU/ml solution for injection in a pre-filled syringe  
The syringes contain 1 ml (2,000 IU) of solution.

Binocrit 4,000 IU/0.4 ml solution for injection in a pre-filled syringe  
The syringes contain 0.4 ml (4,000 IU) of solution.

Binocrit 10,000 IU/ml solution for injection in a pre-filled syringe  
The syringes contain 1 ml (10,000 IU) of solution.

Binocrit 40,000 IU/ml solution for injection in a pre-filled syringe  
The syringes contain 1 ml (40,000 IU) of solution.

Pack size of 1 or 6 pre-filled syringe(s) with or without a needle safety guard.

Not all pack sizes may be marketed

- *Ingredients*

- *Active ingredient*

Epoetin alfa

- *Inactive ingredients*

Sodium dihydrogen phosphate dihydrate

Disodium phosphate dihydrate

Sodium chloride

Glycine

Polysorbate 80

Hydrochloric acid

Sodium hydroxide

Water for injections

- *MAL number(s)*

2000IU/ml

MAL20112122ACZ

4000IU/0.4ml

MAL20112123ACZ

10000IU/ml

40000IU/ml

MAL20112125ACZ

**Product registration holder**

Sandoz Products Malaysia Sdn. Bhd.

Unit 1202, Level 12, Uptown 1,

No. 1, Jalan SS 21/58, Damansara

Uptown,

47400 Petaling Jaya, Selangor, Malaysia

**Date of revision**

28 January 2025

**Serial number**

NPRA (R3/01) 27012025/0345