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Binocrit (*epoetin alfa*)

An overview of Binocrit and why it is authorised in the EU

What is Binocrit and what is it used for?

Binocrit is a medicine used for the following:

- to treat anaemia (low red blood cell counts) that is causing symptoms in patients with 'chronic kidney failure' (long-term, progressive decrease in the ability of the kidneys to work properly) or other kidney problems;
- to treat anaemia in adults receiving chemotherapy for certain types of cancer and to reduce the need for blood transfusions;
- to increase the amount of blood that can be taken in adult patients with moderate anaemia and normal blood iron levels who are going to have an operation and donate their own blood before surgery (autologous blood transfusion);
- to reduce the need for blood transfusions in adults with moderate anaemia who are about to undergo major orthopaedic (bone) surgery, such as hip surgery. It is used in patients with normal blood iron levels who could experience complications from a blood transfusion, if they do not donate their own blood before surgery and are expected to lose 900 to 1,800 ml of blood;
- to treat anaemia in adults with myelodysplastic syndromes (conditions in which the production of healthy blood cells is defective). Binocrit is used when patients are at low or intermediate risk of developing acute myeloid leukaemia and have low levels of the natural hormone erythropoietin.

Binocrit contains the active substance epoetin alfa and is a 'biosimilar medicine'. This means that Binocrit is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Binocrit is Eprex/Erypo. For more information on biosimilar medicines, see here.

How is Binocrit used?

Binocrit can only be obtained with a prescription and treatment must be started under the supervision of a doctor who has experience in the management of patients with the conditions that Binocrit is used for. The iron levels of all patients should be checked to make sure that they are not too low, and iron supplements given if necessary.

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Binocrit is available in pre-filled syringes of various strengths and is given as an injection into a vein or as an injection under the skin, depending on the condition for which the patient is being treated. The injection under the skin may be given by the patient or their carer if they have been appropriately trained. The dose, the frequency of injection and how long it is used for also depend on why Binocrit is being used and on the patient's bodyweight, and are adjusted according to how well the medicine is working.

For patients with kidney failure, myelodysplastic syndromes or receiving chemotherapy, haemoglobin levels should remain within the recommended range (between 10 and 12 grams per decilitre in adults and between 9.5 and 11 g/dl in children). Haemoglobin is the protein in red blood cells that carries oxygen around the body. For these patients, the lowest dose that provides adequate control of symptoms should be used.

For more information about using Binocrit, see the package leaflet or contact your doctor or pharmacist.

How does Binocrit work?

The active substance in Binocrit, epoetin alfa, is a copy of a hormone called erythropoietin, and works in exactly the same way as the natural hormone to stimulate the production of red blood cells in the bone marrow. Erythropoietin is produced by the kidneys. In patients receiving chemotherapy or with kidney problems, anaemia can be caused by a lack of erythropoietin, or by the body not responding well enough to natural erythropoietin. In these cases, epoetin alfa is used to increase red blood cell counts. Epoetin alfa is also used before surgery to increase the number of red blood cells and help minimise the consequences of blood loss.

What benefits of Binocrit have been shown in studies?

Laboratory studies comparing Binocrit with the reference medicine Eprex/Erypo have shown that the active substance in Binocrit is highly similar to that in Eprex/Erypo in terms of structure, purity and biological activity. Studies have also shown that giving Binocrit produces similar levels of the active substance in the body to giving Eprex/Erypo.

In addition, Binocrit was shown to be as effective as Eprex/Erypo at increasing and maintaining red blood cell counts in several studies.

Binocrit, injected into a vein, was compared with the reference medicine in one main study involving 479 patients with anaemia caused by kidney problems. All of the patients had been receiving Eprex/Erypo injected into a vein for at least 8 weeks before they were either switched to Binocrit or remained on Eprex/Erypo. The main measure of effectiveness was the change in the levels of haemoglobin between the start of the study and the evaluation period, between weeks 25 and 29. Patients switching to Binocrit maintained haemoglobin levels to the same extent as those continuing with Eprex/Erypo. A further study showed that Binocrit was safe and effective when given under the skin in 416 patients with chronic kidney failure.

Another study showed that Binocrit injected under the skin was as effective in maintaining haemoglobin levels as Eprex/Erypo in 114 cancer patients who were receiving chemotherapy.

Because Binocrit is a biosimilar medicine, the studies on effectiveness and safety of epoetin alfa carried out with Eprex/Erypo do not all need to be repeated for Binocrit.

What are the risks associated with Binocrit?

The most common side effects with Binocrit (which may affect more than 1 in 10 people) are nausea (feeling sick),diarrhoea, vomiting, fever and headache. Flu-like illness may occur especially at the start of treatment. For the full list of side effects of Binocrit, see the package leaflet.

Binocrit must not be used in the following groups:

- patients who have developed pure red cell aplasia (reduced or stopped red blood cell production) following treatment with any erythropoietin;
- patients with high blood pressure that is not controlled;
- patients undergoing surgery who cannot receive medicines for the prevention of blood clots;
- patients about to undergo major orthopaedic surgery who have severe cardiovascular (heart and blood vessel) problems including a recent heart attack or stroke.

When Binocrit is used for autologous blood transfusion, the restrictions normally associated with this type of transfusion should be observed.

For the full list of restrictions, see the package leaflet.

Why is Binocrit authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Binocrit has a highly similar structure, purity and biological activity to Eprex/Erypo and is distributed in the body in the same way. In addition, studies have shown that the effects of the medicine are equivalent to those of Eprex/Erypo in increasing and maintaining blood cell counts in patients with chronic kidney failure or undergoing chemotherapy. Therefore the Agency's view was that, as for Eprex/Erypo, the benefit of Binocrit outweighs the identified risk and it can be authorised.

What measures are being taken to ensure the safe and effective use of Binocrit?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Binocrit have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Binocrit are continuously monitored. Side effects reported with Binocrit are carefully evaluated and any necessary action taken to protect patients.

Other information about Binocrit

Binocrit received a marketing authorisation valid throughout the EU on 28 August 2007.

Further information on Binocrit can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports.

This overview was last updated in 08-2018.