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EPAR summary for the public

Retacrit

epoetin zeta

This document is a summary of the European Public Assessment Report (EPAR) for Retacrit. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Retacrit.

What is Retacrit?

Retacrit is a solution for injection. It is available in prefilled syringes containing between 1,000 and 40,000 international units (IU) of the active substance, epoetin zeta.

Retacrit is a 'biosimilar' medicine. This means that Retacrit is similar to a biological medicine (the 'reference medicine') that is already authorised in the European Union (EU), and contains a similar active substance to the reference medicine. The reference medicine for Retacrit is Eprex/Erypo, which contains epoetin alfa. For more information on biosimilar medicines, see the question-and-answer document here.

What is Retacrit used for?

Retacrit is used in the following situations:

- to treat anaemia (low red blood cell counts) that is causing symptoms in patients with chronic renal 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 to treat certain types of cancer and to reduce the need for blood transfusions;
- to increase the amount of blood that patients with moderate anaemia can self-donate before surgery, so that their own blood can be given back to them during or after surgery;
- to reduce the need for blood transfusions in patients with moderate anaemia about to undergo major bone surgery (such as a hip or knee replacement).

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The medicine can only be obtained with a prescription.

How is Retacrit used?

Treatment with Retacrit must be started under the supervision of doctors who have experience in the management of patients with the conditions that the medicine is used for.

For patients with kidney problems, Retacrit can be injected into a vein or under the skin. For patients receiving chemotherapy, it must be injected under the skin, and for patients about to undergo surgery, it must be injected into a vein. The dose, the frequency of injection and how long Retacrit is used for depend on why it is being used, and are adjusted according to the patient's response. For patients with chronic renal failure 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. The lowest dose that provides adequate control of symptoms should be used.

The iron levels of all patients should be checked before treatment to make sure that they are not too low, and iron supplements should be used throughout treatment. Retacrit can be injected under the skin by the patient or their carer if they have been trained appropriately. For full details, see the package leaflet.

How does Retacrit work?

A hormone called erythropoietin stimulates the production of red blood cells from 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 enough to the erythropoietin it has naturally. In these cases, erythropoietin is used to replace the missing hormone or to increase red blood cell counts. Erythropoietin is also used before surgery to increase the number of red blood cells to help patients produce more blood for self-donation.

The active substance in Retacrit, epoetin zeta, is a copy of human erythropoietin and works in exactly the same way as the natural hormone to stimulate red blood cell production. It is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes it able to produce epoetin zeta.

How has Retacrit been studied?

Retacrit was studied to show that it is comparable with the reference medicine, Eprex/Erypo, in experimental models and in humans.

Retacrit, injected into a vein, was compared with the reference medicine in two main studies involving 922 patients who had anaemia associated with chronic renal failure requiring haemodialysis (a technique for removing waste products from the blood). The first study compared the effects of Retacrit with those of Eprex/Erypo in correcting red blood cell counts in 609 patients over 24 weeks. The second study compared the effects of Retacrit with those of Eprex/Erypo in maintaining red blood cell counts in 313 patients. All of the patients in the second study had been receiving treatment with Eprex/Erypo for at least three months before they were either switched to Retacrit or remained on Eprex/Erypo for 12 weeks. After that, the two groups switched to receiving the other medicine for a further 12 weeks. In both studies, the main measures of effectiveness were the levels of haemoglobin during treatment, as well as the dose of epoetin received.

The company also presented the results of two studies looking at the effects of Retacrit injected under the skin: one involved 261 cancer patients receiving chemotherapy, and the other compared Retacrit with Eprex/Erypo in 462 patients with anaemia caused by kidney problems.

What benefit has Retacrit shown during the studies?

Retacrit was as effective as Eprex/Erypo in correcting and maintaining red blood cell counts. In the correction study, haemoglobin levels were around 11.6 g/dl during the last four weeks of the study, having risen from around 8.0 g/dl before treatment. In the study of patients already being treated with an epoetin, haemoglobin levels were maintained at around 11.4 g/dl when the patients were receiving Retacrit and when they were receiving Eprex/Erypo. In both studies, the dose of epoetin received was similar with both medicines.

Retacrit was also effective when it was injected under the skin. The study in patients receiving chemotherapy showed that Retacrit brought about similar improvements in haemoglobin levels as those reported in the scientific literature for other epoetins. Retacrit was also as effective as the reference medicine in patients with kidney problems.

What is the risk associated with Retacrit?

As with other medicines containing an epoetin, the most common side effect with Retacrit is an increase in blood pressure, which can sometimes lead to symptoms of encephalopathy (brain problems) such as sudden stabbing migraine-like headache and confusion. Retacrit can also lead to skin rash and influenza (flu)-like symptoms. For the full list of all side effects reported with Retacrit, see the package leaflet.

Retacrit should not be used in people who may be hypersensitive (allergic) to epoetin zeta or any of the other ingredients. It must not be used in patients who have developed pure red cell aplasia (reduced or stopped red blood cell production) following treatment with any erythropoietin, patients with hypertension (high blood pressure) that is not controlled, patients about to undergo surgery who have severe cardiovascular (heart and blood vessel) problems including a recent heart attack or stroke, or patients who cannot receive medicines to prevent blood clots.

Retacrit must not be used prior to major bone surgery in patients who have a severe disease affecting their arteries or their blood vessels in the heart, neck or brain, including patients who have recently had a heart attack or stroke.

Why has Retacrit been approved?

The CHMP concluded that, in accordance with EU requirements, Retacrit has been shown to have a comparable quality, safety and efficacy profile to Eprex/Erypo. Therefore, the CHMP's view was that, as for Eprex/Erypo, the benefit outweighs the identified risks. The Committee recommended that Retacrit be given marketing authorisation.

Other information about Retacrit:

The European Commission granted a marketing authorisation valid throughout the EU for Retacrit on 18 December 2007.

The full EPAR for Retacrit can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Retacrit, read the Package Leaflet (also part of the EPAR).

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