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Silapo (*epoetin zeta*)

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

What is Silapo and what is it used for?

Silapo is a medicine used for the following:

- to treat anaemia (low red blood cell counts) that is causing symptoms in patients with chronic renal failure (long-term, decreasing 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 adults with moderate anaemia who are about to have 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). Silapo is used when patients are at low or intermediate risk of developing acute myeloid leukaemia and have low levels of the natural hormone erythropoietin.

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

How is Silapo used?

Silapo 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 Silapo is approved for. The iron levels of all patients should be checked and iron supplements given if necessary.

Silapo is available in pre-filled syringes and is injected either into a vein or 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 a carer if they have been trained. The dose, how often it is given and how long it is used

for also depend on why Silapo 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 who are receiving chemotherapy, haemoglobin levels should remain within the recommended range. Haemoglobin is the protein in red blood cells that carries oxygen around the body. For these patients, the lowest dose that controls the symptoms well enough should be used.

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

How does Silapo work?

The active substance in Silapo, epoetin zeta, is a copy of a hormone called erythropoietin, and works in 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 zeta is used to increase red blood cell counts. Epoetin zeta is also used before surgery to increase the number of red blood cells and help minimise the consequences of blood loss.

What benefits of Silapo have been shown in studies?

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

Silapo, injected into a vein, was as effective as Eprex/Erypo in correcting and maintaining red blood cell counts in two main studies involving 922 patients who had anaemia associated with chronic renal failure requiring haemodialysis (a procedure for removing waste products from the blood). The first study compared the effects of Silapo with those of Eprex/Erypo in correcting red blood cell counts in 609 patients over 24 weeks. During the last 4 weeks of the study haemoglobin levels were around 11.6 g/dl, having risen from around 8.0 g/dl before treatment. The second study compared the effects of Silapo with those of Eprex/Erypo in maintaining red blood cell counts in 313 patients. All of the patients in the second study had received treatment with Eprex/Erypo for at least 3 months before they were either switched to Silapo or remained on Eprex/Erypo for 12 weeks. After that, the two groups switched to receiving the other medicine for a further 12 weeks. Haemoglobin levels were maintained at around 11.4 g/dl in both groups.

The company also presented the results of two studies showing that Silapo injected under the skin is as effective as other epoetin medicines: one study involved 261 cancer patients receiving chemotherapy, and the other compared Silapo with Eprex/Erypo in 462 patients with anaemia caused by kidney problems.

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

What are the risks associated with Silapo?

The most common side effects with Silapo (which may affect more than 1 in 100 people) are headache and increased blood pressure. For the full list of side effects of Silapo, see the package leaflet.

Silapo must not be used in the following groups:

- patients who have developed pure red cell aplasia (reduced or stopped red blood cell production) after treatment with any epoetin medicine;
- patients with hypertension (high blood pressure) that is not controlled;
- patients who cannot receive medicines to prevent blood clots;
- patients about to have surgery, including major orthopaedic surgery, and who have severe cardiovascular (heart and blood vessel) problems including a recent heart attack or stroke.

Why is Silapo authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Silapo 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. All these data were considered sufficient to conclude that Silapo will behave in the same way as Eprex/Erypo in terms of effectiveness and safety in its authorised uses. Therefore the Agency's view was that, as for Eprex/Erypo, the benefit of Silapo outweighs the identified risk and it can be authorised.

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

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

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

Other information about Silapo:

Silapo received a marketing authorisation valid throughout the EU on 18 December 2007.

Further information on Silapo can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/Silapo

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