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EPAR summary for the public

Rienso

ferumoxytol

This is a summary of the European public assessment report (EPAR) for Rienso. 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 Rienso.

What is Rienso?

Rienso is an iron preparation that contains the active substance ferumoxytol. It is available as a solution for infusion (drip) into a vein.

What is Rienso used for?

Rienso is used to treat anaemia (low levels of red blood cells or haemoglobin) caused by a deficiency of iron in patients with chronic kidney disease (long-term, progressive decrease in the ability of the kidneys to work properly).

The medicine can only be obtained with a prescription.

How is Rienso used?

Rienso should only be given when healthcare professionals trained to manage anaphylactic (severe allergic) reactions and full resuscitation facilities are available.

Rienso is given as an infusion into a vein lasting at least 15 minutes. Depending on the severity of the anaemia and the patient's body weight, a second infusion may be given two to eight days after the first dose. The doctor should ensure that the patient is observed for adverse reactions for at least 30 minutes following the infusion.

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Patients should have their blood and iron levels tested after at least one month following treatment. To maintain normal haemoglobin levels, patients may be re-treated with Rienso if they are confirmed to be lacking iron.

How does Rienso work?

Iron deficiency is a common cause of anaemia in patients with long-term kidney disease and is itself caused by many factors including the poor absorption of dietary iron from food.

The active substance in Rienso, ferumoxytol, is an iron-containing compound. When injected into the blood, it is taken up by cells in the liver, spleen and the bone marrow, at which point the iron is released from the compound and replaces the body's depleted iron stores. With the iron stores replenished, the body can produce more haemoglobin, which will help correct the anaemia.

How has Rienso been studied?

Three main studies involving 838 chronic kidney disease patients with iron deficiency anaemia have been carried out to compare Rienso with an iron treatment taken by mouth. The main measure of effectiveness was how much haemoglobin levels (measured in grams per decilitre, g/dl) rose after five weeks.

What benefit has Rienso shown during the studies?

Rienso was more effective at increasing haemoglobin levels than the iron treatment taken by mouth. In all three studies, patients taking Rienso had higher average increases in haemoglobin: 1.2 g/dl versus 0.5 g/dl; 0.8 g/dl versus 0.2 g/dl; and 1.0 g/dl versus 0.5 g/dl.

What is the risk associated with Rienso?

In studies with Rienso, side effects were seen in 7.9% of patients taking the medicine, of which 0.2% were considered serious. The most frequently reported side effects were symptoms affecting the gut (diarrhoea, constipation, nausea and vomiting), headache, dizziness and hypotension (low blood pressure), all occurring in less than 2.5% of patients. Serious cases of hypersensitivity (allergic reaction) or hypotension were uncommon and were seen in 0.2% of patients. For the full list of all side effects reported with Rienso, see the package leaflet.

Rienso must not be used in people with a history of drug allergy, including allergy to ferumoxytol or any other iron preparation. It must not be used in patients with evidence of excess iron in the body or in patients whose anaemia is not caused by iron deficiency. For the full list of restrictions, see the package leaflet.

Why has Rienso been approved?

The CHMP decided that Rienso's benefits are greater than its risks and recommended that it be given marketing authorisation. Rienso was shown to be superior to iron taken by mouth in treating iron deficiency anaemia in patients with chronic kidney disease. The increase in haemoglobin seen in the main studies was considered by the CHMP to be a valuable improvement and comparable to what is obtained with standard intravenous iron preparations.

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

A risk management plan has been developed to ensure that Rienso is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Rienso, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that market Rienso will provide educational material to patients and doctors expected to use Rienso, with information on the risk of allergic reactions. The company will also carry out studies to further characterise this risk.

Other information about Rienso

The European Commission granted a marketing authorisation valid throughout the European Union for Rienso on 15 June 2012.

The full EPAR for Rienso 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 Rienso, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2015.