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EPAR summary for the public

Fexeric

ferric citrate coordination complex

This is a summary of the European public assessment report (EPAR) for Fexeric. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Fexeric.

For practical information about using Fexeric, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fexeric and what is it used for?

Fexeric is a medicine used to control hyperphosphataemia (high levels of phosphate in the blood) in adults with long-term kidney disease. It contains the active substance ferric citrate coordination complex.

How is Fexeric used?

Fexeric is available as 1 g tablets. The recommended starting dose is 3 to 6 tablets per day, taken in divided doses together with meals. The maximum dose is 12 tablets per day. Blood-phosphate levels should be monitored regularly during treatment. Patients should keep to their prescribed low-phosphate diets.

The medicine can only be obtained with a prescription. For further information, see the package leaflet.

How does Fexeric work?

Patients with severe kidney disease have difficulty eliminating phosphate from their bodies. A build-up of phosphate leads to hyperphosphataemia and in the long-term can cause complications such as heart and bone disease.

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The active substance in Fexeric, ferric citrate coordination complex, is a phosphate binder. When taken with meals, the iron contained in Fexeric binds to phosphate from food in the gut, forming a compound that is then eliminated in the stools. This prevents the phosphate from being absorbed into the body and helps to keep down the phosphate levels in the blood.

What benefits of Fexeric have been shown in studies?

Fexeric was shown to be effective at controlling blood-phosphate levels in 2 main studies in patients with long-term kidney disease and hyperphosphataemia. Both studies looked at the change in the amount of phosphate in the blood, measured in mg/dl.

In the first study, Fexeric was as effective as sevelamer carbonate, an approved medicine, in lowering phosphate levels in 359 patients with long-term kidney disease: after 12 weeks both treatments resulted in a reduction in phosphate levels of around 2 mg/dl.

In the second study, 149 patients who were not on dialysis received either Fexeric or placebo for 3 months. The study showed that blood-phosphate levels fell on average by 0.7 mg/dl with Fexeric compared with 0.3 mg/dl with placebo.

What are the risks associated with Fexeric?

The most common side effects with Fexeric (which may affect more than 1 in 10 people) are changes in bowel movements (diarrhoea or constipation) and discoloured faeces. Serious side effects were uncommon and mainly affected the gut and stomach. For the full list of all side effects reported with Fexeric, see the package leaflet.

Fexeric must not be used in patients with low blood-phosphate levels, patients who have severe problems with the stomach and gut (such as bleeding from the gut), and those with iron accumulation disorders such as haemochromatosis. For the full list of restrictions, see the package leaflet.

Why is Fexeric approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Fexeric's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that Fexeric is effective at controlling blood-phosphate levels in patients with long-term kidney disease, whether they are on dialysis or not. The overall safety profile was considered acceptable and comparable to other phosphate binders.

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

A risk management plan has been developed to ensure that Fexeric 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 Fexeric, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Fexeric will carry out a study to gain further information on the long-term safety of Fexeric, particularly in older patients.

Further information can be found in the summary of the risk management plan.

Other information about Fexeric

The European Commission granted a marketing authorisation valid throughout the European Union for Fexeric on 23 September 2015.

The full EPAR and risk management plan summary for Fexeric 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 Fexeric, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2015.