EMA/14796/2016

Summary of the risk management plan (RMP) for Feraccru (ferric maltol)

This is a summary of the risk management plan (RMP) for Feraccru, which details the measures to be taken in order to ensure that Feraccru is used as safely as possible. For more information on RMP summaries, see here.

This RMP summary should be read in conjunction with the EPAR summary and the product information for Feraccru, which can be found on Feraccru's EPAR page.

Overview of disease epidemiology

Feraccru is a medicine that contains iron in the form of the active substance ferric maltol. It is used to treat anaemia (low levels of red blood cells or haemoglobin) caused by a lack of iron (iron deficiency) in adults with inflammatory bowel disease.

Iron is one of the building blocks of haemoglobin, an essential substance inside red blood cells that stores and carries oxygen. Iron deficiency anaemia is a condition where a lack of iron in the body means there is a decrease in the amount of haemoglobin in red blood cells. Low iron levels are a common complication of inflammatory bowel disease, and iron deficiency anaemia affects up to 76% of patients with Crohn's disease and ulcerative colitis, the two most common forms of inflammatory bowel disease. Iron deficiency anaemia in inflammatory bowel disease is caused by various factors including bleeding and poor absorption of iron from food in the inflamed gut.

Summary of treatment benefits

Feraccru was compared with placebo (a dummy treatment) in one main study involving 128 patients with inflammatory bowel disease who had iron deficiency anaemia, defined as haemoglobin levels below 12.0 grams per decilitre (g/dl). The main measure of effectiveness was how much haemoglobin levels rose after 12 weeks of treatment.

Feraccru was more effective than placebo at increasing haemoglobin levels: in patients taking Feraccru, haemoglobin levels increased on average from 11.0 to 13.2 g/dl whereas in patients given placebo they remained around 11.1 g/dl. In addition, around 65% of patients given Feraccru achieved normal levels of haemoglobin compared with 10% of those on placebo.

Unknowns relating to treatment benefits

In the main and supporting studies nearly all patients were white and non-hispanic/latino, aged between 18 and 76 (average age: 39-40) with most patients aged under 65. There is no evidence to suggest that results would be any different in non-white patients or in elderly patients over 65 years of age.

Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Side effects involving the stomach and gut (gastrointestinal effects)	The most common side effects with Feraccru (which affect up to 1 in 10 patients) involve the digestive system and include constipation, diarrhoea, nausea (feeling sick), pain in the stomach and flatulence (wind).	Monitoring for early symptoms may help prevent side effects. Patients should talk to their doctor if they experience any side effects. Doctors will be able to advise the patient about the side effects with Feraccru.

Important potential risks

Risk	What is known
Interactions with other medicines	To minimise any interactions that might occur with other medicines, Feraccru capsules should be taken at least two hours apart from other medicines. Feraccru should not be taken with iron given by injection, or with the medicines dimercaprol, chloramphenicol, or methyldopa.
Worsening of disease symptoms	In clinical trials, there were no flare-ups of underlying disease in patients with inflammatory bowel disease treated with Feraccru for 12 weeks, compared with placebo. Furthermore Crohn's disease and ulcerative colitis disease activity scores did not get worse from start of treatment for up to 64 weeks of treatment.
Hypersensitivity and allergic reactions	Some of the ingredients in Feraccru may cause an allergic reaction. Feraccru capsules contain colorants called E110 and E129 which may cause allergic reactions. Patients should not take Feraccru if they are allergic to the active substance ferric maltol or any of the other ingredients.

Missing information

Risk	What is known
Use in patients who are pregnant or breastfeeding	There is no information available on the use of Feraccru in women who are either pregnant or breastfeeding. Patients who are pregnant or breastfeeding should preferably not take Feraccru. Patients who are pregnant or breastfeeding, think they may be pregnant or are planning to have a baby should speak to their doctor or pharmacist before taking this medicine.
Use in patients under 18 years of age	There is no information available on the use of Feraccru in children; Feraccru is not authorised for use in patients under the age of 18 years.

Summary of risk minimisation measures by safety concern

All medicines have a summary of product characteristics (SmPC) which provides physicians, pharmacists and other healthcare professionals with details on how to use the medicine, and also describes the risks and recommendations for minimising them. Information for patients is available in lay language in the package leaflet. The measures listed in these documents are known as 'routine risk minimisation measures'.

The SmPC and the package leaflet are part of the medicine's product information. The product information for Feraccru can be found on Feraccru's EPAR page.

This medicine has no additional risk minimisation measures.

Planned post-authorisation development plan

List of studies in post-authorisation development plan

Study / activity (including study number)	Objectives	Safety concerns / efficacy issue addressed	Status	Planned date for submission of (interim and) final results
Drug-drug interaction study	To investigate drug interactions with Feraccru	Drug-drug interactions	Ongoing	May 2016 for final report
Drug-drug interaction study	Identification of UGT isoenzymes that are responsible for metabolism of maltol	Drug-drug interactions	Ongoing	May 2016 for final report

Studies which are a condition of the marketing authorisation

None of the above studies are conditions of the marketing authorisation.

Summary of changes to the risk management plan over time

Not applicable.

This summary was last updated in 03-2016.