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Feraccru (*ferric maltol*)

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

What is Feraccru and what is it used for?

Feraccru is an iron-containing medicine used to treat iron deficiency (lack of iron) in adults.

Feraccru contains the active substance ferric maltol.

How is Feraccru used?

Feraccru is available as capsules (30 mg). The recommended dose is one capsule taken twice a day, morning and evening, on an empty stomach. Treatment duration depends on the severity of the iron deficiency, but generally at least 12 weeks of treatment are required.

The medicine can only be obtained with a prescription.

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

How does Feraccru work?

The active substance in Feraccru, ferric maltol, is an iron-containing compound. When taken by mouth, it is absorbed by the cells of the gut; the iron is then released from the compound and transported and stored in the body, helping to restore normal levels in patients with iron deficiency. This helps correct reduced production of haemoglobin (the oxygen-carrying pigment in red blood cells), anaemia (low levels of red blood cells) and any symptoms of the condition. Iron is an essential building block for haemoglobin and the body can produce more haemoglobin and correct anaemia once iron stores are replenished.

What benefits of Feraccru have been shown in studies?

Feraccru is effective at increasing haemoglobin levels in patients with iron deficiency and anaemia, (defined as haemoglobin levels lower than 12 g/dl for women and 13 g/dl for men).

In a study of 128 patients, those taking Feraccru for 12 weeks had their haemoglobin levels increase on average from 11.0 to 13.2 g/dl whereas in patients taking placebo (a dummy treatment)

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haemoglobin levels remained at around 11.1 g/dl. In addition, around 65% of patients taking Feraccru achieved normal levels of haemoglobin compared with 10% of those on placebo.

What are the risks associated with Feraccru?

The most common side effects with Feraccru (which may affect up to 1 in 10 people) are symptoms affecting the gut such as abdominal (belly) pain, flatulence (passing wind), constipation, abdominal discomfort and distension, and diarrhoea; these side effects are usually of mild to moderate intensity. Severe side effects include abdominal pain, constipation and diarrhoea. For the full list of side effects of Feraccru, see the package leaflet.

Feraccru must not be used in patients with iron overload disorder (haemachromatosis) or in patients receiving repeated blood transfusions. For the full list of restrictions, see the package leaflet.

Why is Feraccru authorised in the EU?

The European Medicines Agency decided that Feraccru's benefits are greater than its risks and it can be authorised for use in the EU. Feraccru has been shown to be effective in increasing haemoglobin levels in patients with iron deficiency anaemia. Data on how the medicine is absorbed in the body show that Feraccru can also have an effect on patients with iron deficiency who have not already developed anaemia. The safety profile of Feraccru is considered acceptable, with side effects that are mostly mild to moderate in intensity and in line with those of other iron preparations.

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

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

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

Other information about Feraccru

Feraccru received a marketing authorisation valid throughout the EU on 18 February 2016.

Further information on Feraccru can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 03-2018.