PRESCRIBING INFORMATION: Feraccru 30mg hard capsules (ferric maltol)

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing.

Presentation: Red hard capsules. Each capsule contains 30 mg iron (as ferric maltol).

Indication: Feraccru is indicated in adults for the treatment of iron deficiency.

Dosage and administration: ***Adults:*** Feraccru should be taken orally. The whole capsule should be taken on an empty stomach (with half a glass of water). The recommended dose is one capsule twice daily, in the morning and evening. The absorption of iron is reduced when Feraccru is taken with food. Treatment duration will depend on the severity of iron deficiency but generally at least 12 weeks treatment is required. The treatment should be continued as long as necessary to replenish the body iron stores according to blood tests ***Children:*** The safety and efficacy of Feraccru in children (17 years and under) has not yet been established. No data are available. ***Elderly and patients with hepatic or renal impairment*****:** No dose adjustment is needed in elderly patients or patients with renal impairment (eGFR ≥15 ml/min/1.73 m^2). There is no clinical data on patients with impaired hepatic function and/or renal impairment (eGFR <15 ml/min/1.73 m^2).

Contraindications: Hypersensitivity to the active substance or to any of the excipients; haemochromatosis and other iron overload syndromes; patients receiving repeated blood transfusions.

Warnings and precautions: Not recommended for use in patients with inflammatory bowel disease (IBD) flare or in IBD patients with haemoglobin (Hb) levels <9.5 g/dl. Iron deficiency or iron deficiency anaemia (IDA) diagnosis should be made based on blood tests; it is important to investigate the cause of the iron deficiency and to exclude underlying causes of anaemia other than iron deficiency. Feraccru contains lactose and so patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. This product also contains Allura Red AC (E129) and Sunset Yellow FCF (E110); these may cause allergic reactions.

Interactions: Food has been shown to inhibit uptake of Feraccru and so treatment should be taken on an empty stomach. Avoid concomitant administration of Feraccru and IV iron, dimercaprol, chloramphenicol and methyldopa. Feraccru should be given at least 2 to 3 hours apart from: penicillamine, bisphosphonates, ciprofloxacin, entacapone, levodopa, levofloxacin, levothyroxine (thyroxine), moxifloxacin, mycophenolate, norfloxacin, ofloxacin, tetracyclines, calcium and magnesium salts e.g. magnesium trisilicate.

Fertility, pregnancy and lactation: A moderate amount of data on the oral use of ferric iron in pregnant women indicate no malformative nor feto/ neonatal toxicity. Systemic exposure to the intact ferric maltol complex is negligible. Feraccru may be considered during pregnancy if necessary. No effects of oral ferric iron have been shown in breastfed newborns/infants of treated mothers. Ferric maltol is not available systemically and is therefore unlikely to pass into the mother's milk. Feraccru can be used during breastfeeding if clinically needed. There are no data on the effect of ferric maltol on human fertility.

Effects on ability to drive and use machines: Feraccru has no or negligible influence on the ability to drive and use machines.

Undesirable effects: Common side effects: Abdominal pain, flatulence, constipation, abdominal discomfort/distension, diarrhoea, discoloured faeces and nausea. Refer to the SmPC for a full list and frequency of adverse events.

Price and pack sizes: £47.60 for 56 capsules.

Legal category: Prescription Only Medicine.

Marketing Authorisation Number: EU/1/15/1075/001

Marketing Authorisation Holder: Norgine B.V., Antonio Vivaldistraat 150, 1083 HP Amsterdam, Netherlands.

Date of preparation: December 2020

For further information contact: Norgine Pharmaceuticals Limited, Norgine House, Moorhall Road, Harefield, Middlesex, United Kingdom UB9 6NS. Telephone: +44(0)1895 826 606. E-mail: medinfo@norgine.com.

Company reference: UK-HAE-FER-2000095

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Norgine Pharmaceuticals Ltd on:
Tel. +44 (0)1895 826 606
E-mail medinfo@norgine.com