



Package leaflet: Information for the patient

Feraccru 30 mg hard capsules Iron (as ferric maltol)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it onto others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Feraccru is and what it is used for.
2. What you need to know before you take Feraccru.
3. How to take Feraccru.
4. Possible side effects.
5. How to store Feraccru.
6. Contents of the pack and other information.

1. What Feraccru is and what it is used for

Feraccru contains iron (as ferric maltol). Feraccru is used in adults to treat low iron stores in your body. Low iron causes anaemia (too few red blood cells).

2. What you need to know before you take Feraccru

Do not take Feraccru:

- If you are allergic to ferric maltol or any of the other ingredients of this medicine (listed in section 6).
 - If you have any illness causing iron overload or a disturbance in how your body uses iron.
- If you have received multiple blood transfusions.

Warnings and precautions

Before starting treatment, your doctor will use a blood test to make sure that your anaemia is not severe or caused by anything other than iron deficiency (low iron stores).

You should avoid taking Feraccru if you are experiencing a “flare” of your IBD.

Children and adolescents

Do not give Feraccru to children or adolescents 17 years and under as it has not been studied in this age group. Too much iron is dangerous in young children and can be life-threatening.

Other medicines and Feraccru

Tell your doctor or pharmacist if you are taking any other medicines.



You should leave at least 2 hours between taking Feraccru and taking:

- Supplements or medicines that contain magnesium or calcium.
- Some antibiotics, such as ciprofloxacin and tetracycline.
- Bisphosphonates (used to treat bone diseases).
- Penicillamine (used to bind metals).
- Some medicines used to treat Parkinson's disease (entacapone, levodopa) and thyroid problems (levothyroxine).
- Mycophenolate (used with other medicines to prevent the body rejecting transplanted organs).

You should not be given iron by injection or infusion (intravenously) while you are taking Feraccru.

You should not take Feraccru if you are taking dimercaprol (a medicine used to remove toxic metals from the blood), chloramphenicol (used to treat bacterial infections), or methyldopa (used to treat high blood pressure).

Pregnancy and breast-feeding

You should preferably not take Feraccru if you are pregnant or if you are breast-feeding your baby.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Feraccru is unlikely to have any effect on the ability to drive and use machines.

Feraccru capsules contain lactose, Sunset Yellow FCF (E110) and Allura Red AC (E129). *Lactose:* if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sunset Yellow (E110) and Allura Red (E129): may cause allergic reactions.

3. How to take Feraccru

Always take these capsules exactly as your doctor has told you.

Adults (18 years and over in age)

Take Feraccru on an empty stomach with half a glass of water (one hour before a meal, or at least 2 hours after a meal). The recommended dose is one capsule (30 mg) taken twice a day, morning and evening.

Swallow the capsules whole.

If you take more Feraccru than you should

Taking too much Feraccru can make the person feel sick or be sick and cause bellyache and diarrhoea. Call your doctor or hospital straightaway if you or another person has taken too much Feraccru. Make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

If you forget to take your Feraccru

Skip the missed dose and take the next dose as normal. Do not take a double dose to make up for a forgotten capsule.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.



4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects (may affect up to 1 in 10 people) of Feraccru are:

- Stomach pain
- Flatulence (wind)
- Constipation
- Discomfort or bloating in the stomach
- Diarrhoea
- Nausea (feeling sick)

Uncommon side effects (may affect up to 1 in 100 people) are: thirst, stiff joints, pain in fingers/toes, headache, acne, skin redness, vomiting and increase in bacteria in the small intestine. Blood tests may show increased levels of proteins that break down chemicals in the blood and of a hormone that stimulates the thyroid gland.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via :-

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Feraccru

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP: The expiry date refers to the last day of that month.

Do not use this medicine for more than 45 days after first opening the bottle.

Do not store the capsules above 25°C.



6. Contents of the pack and other information

What Feraccru contains

The active substance is 30 mg of iron as ferric maltol.

The other ingredients are:

- Lactose monohydrate (see section 2)
- Sodium laurilsulfate
- Magnesium stearate
- Colloidal anhydrous silica
- Crospovidone (Type A)
- Gelatin
- Brilliant Blue (E133)
- Allura Red AC (E129) (see section 2)
- Titanium dioxide (E171)
- Sunset Yellow FCF (E110) (see section 2)

What Feraccru looks like and contents of the pack

Feraccru is a red hard capsule containing a reddish-brown powder.

Feraccru is available in bottles, each containing 56 capsules.

Marketing Authorisation Holder

Norgine B.V.
Antonio Vivaldistraat 150
1083 HP Amsterdam
Netherlands

Manufacturer

Patheon France
40 boulevard de champaret
38300 Bourgoin-Jallieu
FRANCE

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Norgine Pharmaceuticals Ltd
medinfo@norgine.com
+ 44 (0)1895 826 606

This leaflet was last revised in 12/2018

Other sources of information

If you need the information on this leaflet in an alternative format, such as large text, please ring Medical Information on 01895 826 606

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.