Package leaflet: Information for the user
Ferofix 100 mg chewable tablets
Iron (III) hydroxide polymaltose complex

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 only. Do not pass it on to 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 Ferofix is and what it is used for

Ferofix contains the active substance iron, in the form of iron (III) hydroxide polymaltose complex.
Iron is an essential element required for the oxygen-carrying capacity of haemoglobine (the red pigment in the blood cells) and of myoglobin (the red pigment in muscle tissue). In iron deficiency the contents of the pigment are decreased and, if the iron deficiency persists, iron deficiency anemia (low level of hemoglobin and depletion of red blood cells) will occur.

Ferofix is used in the treatment of iron deficiency in adults and adolescents above the age of 12.

2. What you need to know before you take Ferofix

Do not take Ferofix
- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6),
- if iron is overloaded in your body (e.g. hemochromatosis or hemosiderosis),
- if you have problems in uptake of iron in your body, (e.g. thalassemia),
- if you have anemia not caused by iron deficiency (e.g. haemolytic anemia – due to hemolysis, with abnormal breakdown of red blood cells – or megaloblastic anemia – a blood disorder with very large red blood cells).

Warnings and precautions
Talk to your doctor or pharmacist before taking Ferofix.
Anemia can be caused by infections and tumors. Iron cannot be used until recovery of the primary disease. Talk to your doctor if you have a chronic infection or tumor.
During therapy with Ferofix stools may be colored dark, which is harmless.
Iron-based preparations can cause poisoning, especially in children. Talk to your doctor if you take iron supplementation.

Children
Ferofix is not intended for use by children aged 12 years old and younger.

Other medicines and Ferofix
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
You should not take iron orally and intravenously (drip in a vein) at the same time. The uptake or oral iron is significantly decreased when taken together.
No other changes of effects when taken together with other medicines are likely to occur.

Ferofix with food and drink
<Invented name> is taken preferably with food, for better absorption.

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

Use of Ferofix during pregnancy is not likely to cause any adverse effects for the fetus or the woman.
Use of Ferofix during breast-feeding is not likely to cause any adverse effects for the child.

Driving and using machines
Ferofix has no influence on the ability to drive and use machines.

Ferofix contains glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ferofix

Always take this medicine exactly as your doctor has told you. Check with your doctor, if you are not sure.

Depending on how serious your condition is, your doctor will decide on your individual dose.

The recommended dose is:

Children
Ferofix is not intended for use by children aged 12 years old and younger.

Adults and adolescents over 12 years:
Iron deficiency:
1 to 3 tablets daily depending on the severity of the iron deficiency.
During treatment your doctor will check your response to the treatment by blood tests, and adjust the dose if necessary.

Duration of treatment
Duration of treatment may vary depending on the condition for which you take Ferofix. Your doctor will therefore discuss with you how long you need to take it.

Administration
You should take the tablets with a glass of water. It is recommended to take the tablets during or immediately after a meal for better absorption. Ferofix chewable tablets can be chewed or swallowed whole.

If you take more Ferofix than you should

Iron-based preparations can cause poisoning, especially in children.
Symptoms of overdose include: vomiting, vomiting of blood, abdominal pain, lethargy (a symptom that causes you to feel sleepy or fatigued), acute liver failure, coagulopathy (a condition in which the blood's ability to clot is impaired), kidney injury, metabolic acidosis (a clinical disturbance characterized by an increase in plasma acidity), shock, scars in stomach and pyloric stricture (narrowing of the opening from the stomach to the first part of the small intestine). Acute liver failure and cardiovascular collapse are the main causes of death due to iron overdose.
Contact your doctor or pharmacist if you have taken too much of this medicine, or if a child has taken it by mistake.

If you forget to take Ferofix
Take your next dose as scheduled. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Ferofix
For the treatment to be successful, Ferofix should be taken regularly at the dose prescribed by your doctor. Do not change, interrupt or stop the treatment without consultation.

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.
While you are taking Ferofix, you may experience one or more of the following side effects with the following frequencies:

Very common (may affect more than 1 in 10 people):
- dark colouration of the stool

Common (may affect up to 1 in 10 people):
- diarrhea,
- nausea,
- digestive disorders

Uncommon (may affect up to 1 in 100 people):
- vomiting,
- constipation,
- abdominal pain,
- discoloration of teeth
- rash,
- itching,
- headache

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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ferofix

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 blister and the carton after

EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ferofix contains

- The active substance is iron (III) hydroxide polymaltose complex. Each tablet contains iron (III) hydroxide polymaltose complex equivalent to 100 mg iron.

- The other ingredients are: sodium cyclamate (E952), vanillin, macrogol (E1521), white chocolate flavour, dextrates hydrated, cellulose microcrystalline (E460) and talc (E553b).

What Ferofix looks like and contents of the pack
Ferofix 100 mg chewable tablets are beige/brown spotted, round tablets.
Pack sizes: The tablets are available in blisters of 10, in carton boxes with 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[<To be completed nationally>]

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: <Invented Name> 100 mg chewable tablets
Denmark: <Invented Name> 100 mg chewable tablets
Finland: <Invented Name> 100 mg chewable tablets
France: <Invented Name> 100 mg chewable tablets
Italy: <Invented Name> 100 mg chewable tablets
Netherlands: <Invented Name> 100 mg chewable tablets
Norway: <Invented Name> 100 mg chewable tablets
Slovakia: <Invented Name> 100 mg chewable tablets
Spain: <Invented Name> 100 mg chewable tablets
Sweden: Ferofix 100 mg chewable tablets

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