

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ferrum Lek

100 mg chewable tablet

DEXTRIFERON

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Ferrum Lek is and what it is used for
2. Before you take Ferrum Lek
3. How to take Ferrum Lek
4. Possible side effects
5. How to store Ferrum Lek
6. Further information

1. WHAT FERRUM LEK IS AND WHAT IT IS USED FOR

Iron is present in the body in red blood cells, muscles and enzymes. Iron deficiency can cause chronic fatigue, reduced concentration, irritability, nervousness, headache, loss of appetite, weak immune system and increased susceptibility to infections, paleness, cracks at the corners of the lips (sores), dry skin, hair and nails.

Ferrum Lek contains iron in the form of the iron (III) hydroxide in hydrocarbon polymer (polimaltoza). This prevents iron to cause any damage to the digestive system. It also impedes the interaction of iron and food. The structure of the complex iron (III) hydroxide with polimaltozom is similar to the natural form with ferritin, the protein that serves for storing iron. Because of this similarity, iron is absorbed by natural mechanisms.

Ferrum Lek is intended for:

- treatment of iron deficiency
- treatment of anemia caused by lack of iron (the visible lack of iron),
- preventing the iron deficiency in pregnancy (prophylactic treatment).

2. BEFORE YOU TAKE FERRUM LEK

Do not take Ferrum Lek

- If you are hypersensitive to any component of the medicine (see section 6 for more information)
- If you have a high amount of iron in the body (e.g. hemochromatosis, hemosiderosis),
- If you have abnormal exploitation of iron (e.g. Anemia due to lead poisoning, sideroachrestic anemia, Thalassemia),
- If you have Anemia caused by lack of iron (e.g., hemolytic anemia).

Take special care with Ferrum Lek

Talk with your doctor or pharmacist before using Ferrum Lek.

In case of anemia which is a consequence of the infection (inflammation) or malignant (cancer) disease, contact your doctor before using this medicine.

If you use Ferrum Lek in children who are younger than 12 years, lower dose of this medicine is more appropriate, so use the syrup instead of tablets (see section 3. How to use Ferrum Lek 50mg / 5ml).

During the use of Ferrum Lek and other iron products, you may experience dark coloration of stools, but it does not have clinical significance.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

So far there were no observed interactions. Iron is a complex bound, and therefore ionic interactions with food ingredients (oxalates (in vegetables), tannins (in tea), etc.) or medicines (tetracyclines, antacids) are unlikely.

The test for the detection of occult bleeding (selective for hemoglobin) is not affected, so the treatment of iron does not need to be interrupted.

Ferrum Lek syrup does not change the color of tooth enamel.

Co-administration with other pharmacological forms of medicines containing iron (injections or tablets) should be avoided, therefore, tell your doctor if you are using Ferrum Lek syrup and other medical products that contain iron.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, you think you may be pregnant, or are planning to become pregnant, ask your doctor for advice before using this medicine.

By examining the reproductive ability in animals, the risk for the fetus has not been established. . Based on these tests, there is no evidence that the use during the first trimester is harmful and possible negative impact on the fetus is not likely to occur. In controlled trials in which women after the first trimester of pregnancy were involved shows no adverse effects on the mother and / or infant.

Iron is excreted into breast milk, where it binds to a protein that is present in breast milk. Only a small, unknown amount of iron passes from the complex iron (III) hydroxide with polimaltozom in breast milk and the risk of side effects in infants are small.

Because of this, during pregnancy and breast-feeding, Ferrum Lek syrup should be used only if advised by your doctor.

Driving and using machines

Ferrum Lek does not affect the ability to drive and use machines.

Important information about some of the ingredients of Ferrum Lek

Ferrum Lek contains aspartame

Each Ferrum Lek chewing tablet contains 1.5 mg of aspartame (E951), which is a source of phenylalanine. This medicine may harm patients with phenylketonuria.

3. HOW TO TAKE FERRUM LEK

Always take this medicine exactly as your doctor has prescribed. If you are not sure you need to check with your doctor or pharmacist.

Dosage and duration of treatment will vary, depending on the iron deficiency.

Doses are also listed in the table.

Method of administration

- take Ferrum Lek during or immediately after meal. The daily dose can be divided into several meals, or can be taken at once.
- Ferrum Lek Chewable tablets should be chewed or swallowed whole.

State of disease with present symptoms due to a lack of iron (the manifest form)

The treatment should last three to five months. A doctor may also prescribe you a longer treatment, depending on the laboratory analysis of the values of your blood.

Dosing of Ferrum Lek Chewable tablet

Children older than 12 years of age, adults and lactating women: the usual daily dose is 1 to 3 chewable tablets.

Pregnant women: 2 to 3 chewable tablets daily. Then, at least until the end of pregnancy, 1 chewing tablet per day.

A lack of iron without clearly expressed symptoms of the disease (latent)

The treatment lasts approximately one to two months.

Dosing of Ferrum Lek Chewable tablet

Infants up to the first year of life: the dose is so small that a treatment with tablets or syrup is not possible.

Children from 1 to 12 years of age: treatment with tablets is not possible.

Children older than 12 years of age, adults and lactating women: 1 tablet per day.

Pregnant women: 1 tablet per day.

Prevention of a lack of iron in pregnant women: 1 chewable tablet per day.

Table: daily dosage of the medicine for the prevention and treatment of iron deficiency

The other ingredients are

Dextrate
Macrogol 6000
Aspartame (E951)
Talc (E553b)
Chocolate flavor.

What Ferrum Lek looks like and contents of the pack

Ferrum Lek 100 mg chewable tablets are available in a box with 3 double strips of 10 tablets each containing chewing tablets.

Each tablet contains 100 mg of iron in the form of a complex iron (III) hydroxide with polymaltose (dextriferon). The tablets are brownish-white, interspersed, round, flattened tablets with beveled edges.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Lek farmacevtska družba d. d., Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

Lek farmacevtska družba d. d., Verovškova 57, Ljubljana, Slovenia under license by Vifor (International) Inc., St. Gallen, Switzerland