

PACKAGE LEAFLET: INFORMATION FOR THE USER

HEFEROL

350 mg capsule, hard

IRON (II)-FUMARATE

• 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?

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2. Before you take Heferol
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1. WHAT HEFEROL IS AND WHAT IT IS USED FOR

Heferol belongs to a group of medicines called antianemics. This medicine contains a mineral iron, which plays an important role in the acceptance of oxygen and its transport through the body. Iron enters the red blood cells and builds up in hemoglobin. In fact, hemoglobin carries oxygen around the body.

It is used for the treatment of low concentration of iron in the blood or anemia (anemia). Low levels of iron can be a result of insufficient intake of iron through food, poor absorption of iron in the small intestine, pregnancy, breast-feeding or bleeding.

Iron is usually recommended during pregnancy for prophylaxis of anemia.

2. BEFORE YOU TAKE HEFEROL

Do not take Heferol:

- If you have or have had an allergic reaction (hypersensitivity) to some of the ingredients of the medicinal product,
- If you have hemochromatosis,
- if you have hemosiderosis,

- if you have anemia not caused by iron deficiency (hemolytic anemia, aplastic anemia or thalassemia)
- if you have hemoglobinopathy
- simultaneously with parenteral iron.

Be careful with the Heferol if you:

- have anemia which cause is unknown,
- have an ulcer in the stomach or intestines (or other bowel diseases like regional enteritis or ulcerative colitis),
- have removed part of the stomach or the entire stomach,
- have inflammation of the liver (hepatitis),
- receive repeated blood transfusions,
- have prolonged menstrual bleeding and
- have repeated pregnancies.

Taking other medicines with Heferol

Please tell your doctor or pharmacist about all medicines you are taking or have recently taken, including ones that you bought without a prescription.

It is especially important that your doctor or pharmacist know if you are taking:

- antibiotics (quinolones, tetracyclines, chloramphenicol),
- do not take antacids at the same time, preparations containing calcium-phosphates and defrosts carbon, oxalate,
- penicillamine (medicine for rheumatoid arthritis),
- cholestyramine (to reduce cholesterol in your blood or to control diarrhea),
- entacapone, levodopa (medication for Parkinson's disease),
- methyldopa (for high blood pressure),
- thyroxin (thyroid hormone),
- bisphosphonates (bone disease),
- zinc and
- trientin (for Wilson disease).

Sometimes the adjustment is easy, as the two hours space between the dosages is sufficient to avoid problems. However, check with your doctor.

Taking Heferol with food and drink

- It should be taken with plenty of fluids (to avoid constipation),
- can be taken with food (unless it causes stomach problems) and
- avoid simultaneous use of foods such as coffee, tea, eggs, milk and milk products.

Heferol should be taken one hour before or two hours after taking these products. However, the absorption is enhanced with vitamin C.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before you start to use any medicine. No special precautions. Heferol is indicated for iron deficiency during pregnancy and breastfeeding.

Diving and using machines

Heferol has no effect on the ability to drive or use machines.

Important information about some of the ingredients of Heferol

Heferol contains lactose monohydrate. If a doctor told you that you have intolerance to some sugars, before you start taking this medicine, consult your doctor.

Hard gelatin capsule contains: color azorubine (E122) and black (E151) which may cause allergic-type reactions and preservatives methyl parahydroxybenzoate (E218) and propyl (Other)-which can cause an allergic reaction (possibly delayed hypersensitivity reactions).

3. HOW TO TAKE HEFEROL

Always take Heferol exactly as your doctor or health care provider has told you. If you are not sure, consult a doctor or pharmacist.

It is best to take Heferol on an empty stomach, but if it causes stomach discomfort, it can be taken with food. The recommended dose of Heferol is:

Adults and children older than 12 years:

Prophylaxis: 1 capsule a day.

Therapy: 1 capsule twice a day.

Children under 12 years:

not recommended. This product is not intended for the treatment of children.

Elderly patients: the dose for adults.

Pregnant women in the second and third trimester: dose for adults.

The duration of treatment with oral iron is usually determined by the successful discovery of the causes of anemia. Once you discover the cause and treat it, it takes about four to six months to improve anemia. After that, the treatment with iron should stop to avoid the accumulation of iron in the body. Long-term administration should always be under medical control.

If you take more Heferol than you should

The medicine contains iron and should be kept out of the reach of children because an overdose can be fatal.

If you take too many Heferol capsules at once, you must immediately seek medical assistance.

Symptoms of an overdose of iron include epigastric pain, diarrhea, vomiting and collapse.

If you forget to take Heferol

Never take a double dose to replace the missed dose of the medicine.

Take the missed dose as soon as possible, as soon as you notice that you have missed it. If it is almost time for your next dose, wait until then and don't take a forgotten dose.

If you have any further questions on the use of Heferol, talk to your doctor or to the pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The most common, but less serious side effects are digestive system disorders, such as loss of appetite, metallic taste in mouth, nausea, vomiting, constipation or diarrhea, and allergic reactions. Black stools may occur, and that's normal.

If you notice any side effect, talk to your doctor or pharmacist.

5. HOW TO STORE HEFEROL

Keep out of reach and sight of children.

Heferol should not be used after the expiration date stated on the carton. Expiration date refers to the last day of that month.

The product should be stored at temperature up to 30 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to remove medicines that you no longer need. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Heferol contains

- The active substance is iron (II)-fumarate.

Each capsule contains 350 mg of iron (II)-fumarate, which corresponds to 115 mg of elemental iron.

- The other ingredients are: lactose monohydrate; silicon dioxide, colloidal anhydrous; sodium laurylsulfate; magnesium stearate; Composition of gelatin capsules: gelatin; titanium dioxide (E171); color quinolyl-yellow (E104); color azorubine (E122); color zipper-blue (E131); brilliant colors-black (E151); methyl parahydroxybenzoate (E218); propyl parahydroxybenzoate (Other).

How Heferol looks like and contents of the pack

Heferol capsules are a matt ivory/matt dark green hard gelatin capsules, filled with red brownish powder and white admixture.

Capsules are packaged in blister pack of transparent PVC/PVdC/YOU/Al foil, each containing 10 tablets.

The box contains 30 capsules (2 blisters), along with the attached instructions.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Alkaloid AD

Bulevar Aleksandar Makedonski 12, Skopje, Republic of Macedonia

Manufacturer of the medicinal product

Alkaloid AD

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