PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Ferripel-3 Syrup, 50 mg/5 ml

Each 5 ml contains:
Iron (as Iron III Hydroxide Polymaltose Complex) 50 mg
Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and section 2 "Important information about some ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
Use the medicine according to the instructions in the dosage section of this leaflet.
Consult the pharmacist if you have further questions. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after three weeks.

1. What is the medicine intended for?

The medicine is intended for prevention and treatment of anemia caused by iron deficiency.
Therapeutic class: Iron replacement preparations.
Iron is an essential constituent of hemoglobin, myoglobin and iron-containing enzymes. Iron deficiency may cause the following general symptoms: excessive fatigue, impaired mental function, irritability, anxiety, headaches, loss of appetite, weakening of the immune system, conspicuous paleness, cracks in the corners of the mouth, dry skin, split hairs and brittle fingernails.

2. Before treatment with the medicine:

☒ Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains.
- If you have an excess of iron in your body (e.g., an excess of iron caused by a rare disease of iron build-up, which may lead to accumulation of iron in the tissues).
- If you have problems with efficient utilization of iron (e.g., when anemia is caused by insufficient utilization of iron).
- In states of anemia that are not caused by iron deficiency (e.g., anemia caused by increased hemoglobin breakdown or due to vitamin B12 deficiency).

❗ Special warnings regarding the use of the medicine

Before treatment with Ferripel-3 syrup, inform the doctor if:

- You have an infection or a tumor.
- You have recently been treated or you might be treated in the future with injected iron preparations. Using this type of iron preparations during treatment with this medicine is not recommended.
- You have received blood transfusions, since there is a risk for an excess of iron due to receiving additional iron.
- You have other diseases or allergies.

❗ Tests and follow-up:

Before starting to use the medicine, the doctor will refer you for a blood test to check your blood iron and hemoglobin levels. If your symptoms are not caused by iron deficiency, this medicine will not be effective for you.
During treatment with this medicine the doctor will carry out periodic examinations, and may also refer you for blood tests. This referral is normal and should not concern you.

❗ Drug-drug interactions:

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist.

❗ Use of the medicine and food:

The medicine should be taken during or right after a meal. This medicine may be mixed before administration with fruit or vegetable juice or with baby food. The slight change in color does not impair the effect or taste.

❗ Pregnancy, breastfeeding and fertility:

No adverse effects of Ferripel-3 Syrup have been observed on the fetus or on women during pregnancy.
It is unknown whether iron passes into breastmilk.
If you are pregnant, trying to become pregnant or breastfeeding, consult the doctor before using the medicine.

❗ Driving and operating machinery:

Ferripel-3 Syrup does not affect your ability to drive and/or operate machinery.

❗ Important information about some ingredients of the medicine:

The preparation contains 2000 mg/5 ml of sorbitol solution 70%. Sorbitol is a source of fructose. If the doctor told you that you or your child have intolerance to certain types of sugar, or if you have a hereditary intolerance to fructose, a rare hereditary disease in which fructose does not break down, inform the doctor before you or your child use this medicine. Sorbitol may cause digestive system disturbances and has a slight laxative effect.
The syrup contains 1000 mg/5 ml sucrose. This should be noted for diabetic patients. Sucrose may harm your teeth.
The preparation contains ethanol 96%. Each 5 ml of the preparation contains 15.6 mg of ethanol. The ethanol content in the package is 343.2 mg. This small amount of alcohol in the medicine will not have any noticeable effects. The amount of ethanol in 10 ml of this preparation is lower than the amount in 1 ml of beer or 1 ml of wine.
The medicine contains methyl hydroxybenzoate and propyl hydroxybenzoate. These may cause allergic reactions, which may also occur after some time.
The preparation contains less than 23 mg of sodium per 20 ml, and is therefore practically 'sodium-free'.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.
The generally accepted dosage is:
For adults and children above 12 years of age:
For prevention of anemia: 5-10 ml per day.
For treatment of anemia: 10-20 ml per day.
Dosage for children under 12 years of age:
For prevention of anemia: 1 mg (0.1 ml)/kg body weight per day.
Do not exceed a dosage of 15 mg (1.5 ml) per day in infants up to 2 years of age.
For treatment of anemia: up to 2 mg (0.2 ml)/kg body weight, 3 times per day.
Do not exceed the recommended dose.
Method of use:
For accurate dosing, use the included measuring cup.
The daily dose may be taken as a single dose or in divided doses.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, use of Ferripel-3 syrup may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Very common side effects - side effects that occur in more than one out of ten users:
Stool discoloration due to iron excretion. This phenomenon is harmless.
Common side effects - side effects that occur in 1-10 out of 100 users:
Nausea, constipation, diarrhea and abdominal pain.
Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
Vomiting, teeth discoloration, gastritis, itching, rash, hives, redness in the skin, headache.
Rare side effects - side effects that occur in 1-10 out of 10,000 users:
Muscle cramps and pain.
The abovementioned side effects are usually transient.
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.
Reporting side effects:
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
Do not use the medicine after the expiry date (exp. date) appearing on the package and the bottle.
The expiry date refers to the last day of that month.
Storage:
Store in a dark place, at a temperature lower than 25°C. After first opening, the product may be used for 1 month.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Sorbitol solution 70%, Sucrose, Ethanol 96%, Cream Essence, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sodium hydroxide, Dilute hydrochloric acid, Purified water.
What does the medicine look like and what are the contents of the package:
A glass bottle containing 110 ml of dark-brown solution.
Manufacturer/license holder and address:
CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.
This leaflet was revised in 12/2021 in accordance with the Ministry of Health instructions.
Registration number of the medicine in the national drug registry of the Ministry of Health: 1074728826-00

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