

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

This medicine is dispensed without a doctor's prescription

Hemafer

Oral drops (solution)

The active ingredient and its quantity in a dosage unit:

Each 1 ml (20 drops) contains Iron (as Iron III Hydroxide Polymaltose Complex) 50 mg.

Iron III and ferric are synonyms.

Each 1 drop contains 2.5 mg iron.

For a list of the inactive ingredients and allergens in the medicine – see section 6 ("Additional information") and section 2 ("Important information about some of the 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 need more information. Refer to the doctor if the 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.

The medicine is intended to treat and prevent red blood cell deficiency and a decrease in the amount of hemoglobin in the blood (anemia) due to iron deficiency in the blood.

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 using the medicine: Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient or to any of the additional components the medicine contains. The active ingredient is stated in section 1 and the additional ingredients are listed in section 6.
- 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 the medicine, tell 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 other diseases or allergies.
- You have received a blood transfusion, since there is a risk for excess iron due to receiving additional iron.

Tests and follow-up:

Before starting to use the medicine, the doctor will refer you for a 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 the period of 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 interactions:

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor 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 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 the medicine 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 use.

Driving and operating machinery:

The medicine does not affect the ability to drive and/or operate machinery.

Important information about some of the ingredients of the medicine:

The medicine contains methylparaben (also called: methyl parahydroxybenzoate) and propylparaben (also called: propyl parahydroxybenzoate) which may cause allergic reactions, which may also occur after some time.

Each 1 ml of the medicine contains 50 mg sucrose (also called "table sugar"). If you have an intolerance to certain sugars, speak to your doctor before taking this medicine. Sucrose may harm your teeth.

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 over the age of 12 years:

For prevention of anemia: 15-30 drops per day.

For treatment of anemia: 45-60 drops per day.

Dosage for children:

For prevention of anemia: 1 mg iron per day for each 1 kg of the child's body weight.

In infants up to two years of age: do not exceed a dosage of 15 mg iron per day (up to 6 drops in a day).

In preterm infants: 2.5-5 mg iron (1-2 drops) per day for each 1 kg of the preterm infant's body weight.

In accordance with the recommendation of the "Family Care Center" of the Ministry of Health, use the following table, which indicates the dosage based on the child's age.

Child's age	Required dose in drops per day	Required dose in mg iron per day
From 4 months	3 drops	About 7 mg
From 6 months	6 drops	15 mg

For treatment of anemia: up to 6 mg iron (2 drops) per day for each 1 kg body weight.

The daily dose may be taken as a single dose or in divided doses.

Do not exceed the recommended dose.

Method of use:

- Open the cap by turning it counterclockwise.
- Hold the bottle vertically upside-down over a teaspoon until a drop forms at the tip of the bottle's dropper. If no drop is forming, tap the bottle gently with your finger until a drop forms.
- Do not shake the bottle.
- Count the number of drops precisely.
- Pour the measured content of drops in the teaspoon into the baby's mouth. **Do not pour the medicine directly from the bottle into the baby's mouth!**
- Wipe the bottle's top (the dropper) and be sure to put the cap on tightly immediately after use in order to prevent the dropper from clogging.
- The original dropper is calibrated to release a measured and accurate amount with each use. Do not replace the original dropper with another.

If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or to a hospital emergency room 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 a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using this medicine 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 – effects that occur in more than one user out of ten:

Stool discoloration due to iron excretion. This effect is harmless.

Common side effects – effects that occur in 1-10 users out of 100:

Nausea, constipation, diarrhea and abdominal pain.

Uncommon side effects – effects that occur in 1-10 users out of 1,000:

Vomiting, tooth discoloration, gastritis, itch, rash, hives (urticaria), redness in the skin and headache.

Rare side effects – effects that occur in 1-10 users out of 10,000:

Muscle cramps and muscle 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 the 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 label.

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

Storage conditions: store at a temperature below 25°C. Be sure to close the cap tightly after use.

Shelf life after first opening the bottle: can be used for 3 months.

Do not discard medicines in the toilet or domestic trash. Consult with the pharmacist on how to discard unneeded medicines, in order to protect the environment.

6. Additional information:

In addition to the active ingredient, the medicine also contains the following inactive ingredients:

Sucrose, Essence Lemon, Methylparaben, Propylparaben, Polysorbate 80, Water Purified.

What does the medicine look like and what are the contents of the package?

Clear dark brown solution. The solution is packed in a dark glass bottle, with a dropper and a screw cap to close the bottle. Do not take the dropper out of the bottle. Each bottle is packed in a carton box.

Size of the package: the medicine is supplied in a bottle with 30 ml solution.

License holder: Uni-Pharma Kleon Tselis Pharmaceutical Laboratories Ltd., 22 Beit Hadfuss St., Jerusalem 95483.

Owner of rights: Tree of Life Pharma Ltd., P.O. Box 799, Lod 7110604.

Manufacturer: Uni-Pharma Kleon Tselis Pharmaceutical Laboratories S.A., Kifisia, Greece.

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