

PATIENT PACKAGE INSERT IN
ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986

The medicine is dispensed without a
doctor's prescription

Hemafer, Oral drops (solution)

1) NAME, FORM AND STRENGTH OF THE MEDICINE:

Name of the medicine: Hemafer

Form: Oral drops (solution)

**The active ingredient and its amount
per dosage unit:**

1 mL (20 drops) contains iron (as iron III
hydroxide polymaltose complex) 50 mg.
Iron III and Ferric are synonyms.

Each drop contains 2.5 mg iron.

1 mL of the medicine contains 50 mg
sucrose.

For the list of inactive and allergenic
ingredients - see section 6.

**Read this leaflet carefully in its entirety
before using the medicine.**

This leaflet contains concise information
about the medicine. If you have further
questions, refer to the doctor or pharmacist.
The medicine is intended for all ages,
from premature infants, infants, children,
adolescents, adults, to the elderly. The
medicine is intended for men and women
alike. Use it properly. Consult a pharmacist
if you need further information. Refer to the
doctor if the signs of the ailment (symptoms)
worsen or do not improve after a few days.

**Summary of the essential information
about the medicine:**

The medicine treats and prevents blood
red cell deficiency and decreased amount
of hemoglobin in the blood (anemia)
caused by iron deficiency in the blood.
The medicine is intended for all ages,
from premature infants to the elderly.
The dosage of the medicine is determined
by the patient's age or weight. See section
6 for further information.

What is the medicine intended for? The
medicine is intended to treat and prevent red
blood cell deficiency and decreased amount
of hemoglobin in the blood (anemia) caused
by iron deficiency in the blood.

2) BEFORE USING THE MEDICINE:

Do not use the medicine:

- if you are sensitive (allergic) to the
active ingredient or to any of the other
ingredients contained in the medicine.
The active ingredient appears in
section 1 and the additional ingredients
are listed in section 6.
- Do not use this medicine in other
anemic conditions that are not
accompanied by iron deficiency, such as:
hemolytic anemia.
- Do not use the medicine in cases
of iron accumulation in body tissues
(haemochromatosis) (very rare) or in
diseases in which use of available iron
stores in the body is abnormal.

**Special warnings regarding use of the
medicine:**

- Consult a doctor before starting the
treatment if you suffer, or have suffered in
the past, from impaired function of:
the digestive system (e.g., ulcer), the
circulatory system (e.g., coagulation),
diabetes (the preparation contains
sugar), diagnosed blood deficiency or if
you receive repeated blood transfusions.
- If you are sensitive to any food or
medicine, inform the doctor before taking
the medicine.

If you are taking other medicines
including non-prescription medicines and
dietary supplements, tell the doctor or
pharmacist.

Pregnancy and breastfeeding: If you
are pregnant and/or breastfeeding, consult
the doctor to determine the dosage.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's
instructions. Check with the doctor or
pharmacist if you are uncertain.

**The recommended dosage for adults
and adolescents from 12 years of age
and above:** The recommended dosage
is generally:

To prevent anemia: 15-30 drops per day.

To treat anemia: 45-60 drops per day.

**The recommended dosage for children
aged 2 years to 12 years of age:** The
recommended dosage is generally:

To prevent anemia: 1 mg iron per 1 kg of
the child's body weight per day.

To treat anemia: up to 6 mg iron (2 drops)
per 1 kg of the child's body weight per day.
Each drop contains 2.5 mg iron.

**The recommended dosage for infants
up to 2 years of age:** The recommended
dosage is generally up to 15 mg iron per day
(up to 6 drops). Do not exceed this dosage.

**The recommended dosage for
premature infants:** The recommended
dosage is generally 2.5-5 mg iron (1-2 drops)
for each 1 kg of the premature infants's body
weight per day. Do not exceed this dosage.
In accordance with the recommendations
of the Ministry of Health's Baby Clinic
Centers ("Tipat Halav"), use the table
below, which lists dosages according to
the child's age.

Child's age	The required dose in mg iron per day	The required dose in drops per day
From 4 months	Approximately 7 mg	3 drops
From 6 months	15 mg	6 drops

Do not exceed the recommended dose.

Taking the medicine:

- The daily dose can be taken once a day
or in divided doses. Do not exceed the
recommended dose.
- Make sure to measure the dose with the
dropper.
- Wait at least two hours between taking
this medicine and taking antacids or
antibiotics from the tetracycline and
quinolone group.

- When taking dimercaprol (to treat metal
poisoning), it is sufficient to wait 24 hours.

How to use the medicine:

- Take the medicine during or after a meal.
Before taking it, the medicine can be
mixed with fruit and vegetable juices or
baby food.
- Do not shake the medicine before use.
Shaking makes it harder for the drops to
exit the dropper.
- Do not switch the original dropper with
another, since it is calibrated to release
a measured and precise amount at each
use.
- Open the cap by turning counter-
clockwise.
- Hold the bottle vertically, over the
teaspoon, and wait for it to drip.
- If drops do not come out, gently tap the
bottom of the bottle.
- Count the exact number of drops.
- Pour the contents of the measuring
spoon into the baby's mouth. **Do not
drip the medicine directly from the
bottle into the baby's mouth!**
- Wipe the top of the bottle (the dropper)
and make sure to close the cap tightly
immediately after use, to avoid blockage
of the dropper.

Duration of treatment with the medicine:

Do not use this medicine often or for an
extended period without consulting the
doctor. Do not exceed the recommended
dose and the recommended duration of
the treatment.

During the course of treatment with this
medicine, perform blood tests. Refer to
the doctor.

If you took an overdose, or if a child
accidentally swallowed the medicine,
immediately refer to a doctor or proceed
to a hospital emergency room, and bring
the package of the medicine with you.

If you forgot to take this medicine at the
required time, do not take a double dose.
Take the next dose at the usual time and
consult a doctor.

If you accidentally took a double dose, call
the doctor or pharmacist immediately.

Even if there is an improvement in your
condition, do not stop treatment with the
medicine without consulting a doctor or
pharmacist.

**How can you contribute to the success
of the treatment?**

Complete the treatment as recommended
by the doctor.

Do not take medicines in the dark! Check
the label and the dose each time you take
a medicine. Wear glasses if you need them.
If you have further questions regarding
use of the medicine, consult a doctor or
pharmacist.

4) SIDE EFFECTS

As with any medicine, use of this medicine
may cause side effects in some users. Do
not be alarmed by the list of side effects.
You may not suffer from any of them.

**Discontinue use of the medicine and
refer to a doctor immediately if you
experience or suffer from:** severe
stomach pains.

In addition to the desired effect of the
medicine, side effects may occur during
its use, such as: constipation, diarrhea,
nausea, pressure in the upper part of
the stomach and a sensation of fullness,
vomiting, headache, symptoms of an
allergic reaction (asthma, rash), localized
skin reaction (rash, itching), change in stool
color caused by excretion of iron (common),
dark-colored urine (rare), change in the
color of the teeth (rare and reversible). The
above-mentioned side effects are generally
not harmful and are temporary.

If one of the side effects worsens or if you
suffer from a side effect not mentioned in
the leaflet, consult with the doctor.

Side effects can be reported to the
Ministry of Health by clicking on the link
"Report Side Effects of Drug Treatment"
found on the Ministry of Health homepage
(www.health.gov.il) that directs you to the
online form for reporting side effects, or by
entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@moh.gov.il>

5) HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine, and any
other medicine, should be kept in a safe
place out of the reach of children and/or
infants in order to avoid poisoning. Do not
induce vomiting unless explicitly instructed
to do so by the doctor.

Do not use the medicine after the expiry
date (Exp. Date) appearing on the package/
bottle/carton/label. The expiry date refers
to the last day of that month.

Storage conditions: Store at a temperature
below 25°C. Make sure to close the cap
tightly after each use.

Storage after first opening the bottle:
the medicine can be used for 3 months.

6) FURTHER INFORMATION

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

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

1 mL of the medicine contains 50 mg
sucrose.

**What the medicine looks like and
the contents of the package:** The
medicine looks like a dark-brown solution
(occasionally with a red tint). The solution
is packaged in a dark glass bottle, with a
dropper and screw-on cap to close the
bottle. Do not take the dropper out of the
bottle. Each bottle is sealed and packaged
in a carton box.

Package size: A bottle with 30 mL solution.

Registration holder: Uni-Pharma Kion
Tselis Pharmaceutical Laboratories Ltd.,
VAT # 515049666, 22 Beit Haduss Street,
Jerusalem 95483.

Manufacturer: Uni-Pharma, Kifisia,
Greece.

The format of this leaflet was determined
by the Ministry of Health and its content
was checked and approved in 11/2017.

Registration number of the medicine in
the National Drug Registry of the Ministry
of Health: 150.66.33806.00