The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in June 2019

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

The medicine is dispensed without a doctor's prescription

Iron Care

Syrup

Active ingredients and their quantity per dosage unit:

Each 5 ml teaspoonful contains 50 mg of iron (as Iron III Hydroxide Polymaltose Complex)

For a list of inactive ingredients see section 6 "Further Information".

Read the 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.

Keep the leaflet; you may need to read it again.

Use the preparation according to the instructions in the dosage section of this leaflet.

Consult the pharmacist if you need further information.

Consult the doctor if symptoms of iron-deficiency anemia do not disappear after three weeks.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for prevention and treatment of iron-deficiency anemia.

Therapeutic group: Iron

2. BEFORE USING THE MEDICINE:

☒ Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (for a list of the inactive ingredients, see section 6).
- You are suffering from a condition of accumulation of iron in the body tissues (such as rare diseases of iron storage, which may cause an accumulation of iron in the tissues).
- You suffer from iron utilization disorders in your body (such as anemia due to abnormal utilization of iron in the body).
- You are suffering from anemia not caused by iron deficiency (such as anemia caused as a result of increased breakdown of hemoglobin or vitamin B12 deficiency).

Special warnings regarding use of the medicine:

Before treatment with Iron Care, tell the doctor or pharmacist if:

- You are suffering from an infection or a tumor or any other illness.
- You have recently received or are about to receive iron by injection. It is not recommended to use Iron Care together with injectable iron.
- You have received a blood transfusion, which may lead to an excess of iron as a result of receiving the extra iron.
- You suffer from allergies.

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

Use of the medicine and food

Take this medicine during or immediately after a meal.

Before taking the medicine, it can be mixed with fruit and vegetable juices or baby food.

Infants

This medicine is not intended for infants under the age of two years, since this form of administration makes it difficult to measure accurate doses to treat infants.

For treatment in children and infants below the age of two years, you may use drops; refer to the doctor for advice.

Tests and follow up

During the course of treatment with this medicine, blood tests should be undertaken.

Pregnancy and breastfeeding

If you are pregnant, trying to become pregnant or breastfeeding, you should take Iron Care only after consulting with your doctor.

Important information about some of the ingredients of the medicine

The preparation contains about 2500 mg sucrose per teaspoonful (5 ml).

The preparation contains about 750 mg sorbitol 70% per teaspoonful (5 ml).

If you have a known sugar intolerance, consult with the doctor with regard to continuation of treatment with Iron Care.

Long term use (more than two weeks) of a syrup containing sucrose may be harmful to your teeth.

Use of sorbitol may cause abdominal discomfort and have a slight laxative effect.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.

The usual dose is generally:

Adults and children over 12 years of age:

For prevention of anemia: 5-10 ml daily.

For treatment of anemia: 10-20 ml daily.

Dosage in children:

For prevention of anemia: 1 mg (0.1 ml)/kg body weight daily.

For treatment of anemia: up to 2 mg (0.2 ml)/kg body weight 3 times daily.

It is important to measure the dose with a measuring spoon or special measuring flask.

Do not exceed the recommended dose.

The dosage and duration of treatment depend upon the degree of iron deficiency. In cases of **iron deficiency accompanied by anemia,** the duration of treatment can be up to 3-5 months until iron levels return to normal. Treatment of iron deficiency without anemia should continue for a few weeks at the dosage determined, in order to replenish the iron reserves.

In cases of iron deficiency without anemia, treatment lasts for 1-2 months.

The exact duration of treatment is determined by the attending doctor.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by the doctor.

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 the doctor.

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

Do not take medicines in the dark! Check the label and the dose each time you take 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 Iron Care may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Very common side effects: change in stool color caused by iron secretion. This change is no cause for worry.

Common side effects: diarrhea, nausea, gastrointestinal disorders.

Uncommon side effects: vomiting, constipation, abdominal pain, change in tooth color or headache, as well as local skin reactions (itching, rash). These side effects are usually harmless and temporary.

Very rare side effects: Allergic reactions, such as: skin reactions, swelling (edema), or shortness of breath. In these cases, stop using the medicine and consult with a doctor.

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 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://sideeffects.health.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 and sight 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) that appears on the package. The expiry date refers to the last day of that month.

Store at room temperature (25°C). After first opening the bottle, use the contents within a month.

6. FURTHER INFORMATION:

In addition to the active ingredient, the medicine also contains:

Sucrose, Sorbitol solution 70%, Propylene glycol, Methyl hydroxybenzoate, Cream caramel flavor, Propyl hydroxybenzoate, HCl 1M, Purified water.

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

A carton package containing a bottle of 110 ml of black colored solution, with a child-resistant cap.

Manufacturer and license holder and address: Sam-On Ltd., 25 Ehud Kinamon (Ha'avoda) St., Bat-Yam.

This leaflet was checked and approved by the Ministry of Health in: June 2019.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 162-45-34473.