

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

The medicine is dispensed without a doctor's prescription

## FERRO 15

### Syrup

#### Intended for infants

#### Composition:

Each teaspoonful (5 ml) contains:  
Ferrous Gluconate 130 mg (equivalent to Fe<sup>++</sup> 15 mg)  
For a list of the inactive and allergenic ingredients in the preparation - see section 6 "Further information".

**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 not intended for adults.

Refer to the doctor if the signs of the disease (symptoms) worsen or do not improve after a few days.

#### 1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment and prevention of iron deficiency anemia in infants.

#### Therapeutic group

Preparations for treatment of anemia.

#### 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 inactive ingredients - see section 6 "Further information".
- you are sensitive to another medicine containing iron.
- you suffer from other types of anemia not accompanied by iron deficiency such as hemolytic anemia, or another condition that affects the iron in your body.
- traces of blood have appeared in the urine.
- bronze markings have appeared on the skin or you have been told that you have increased stores of iron in your body.
- you are suffering from a recently diagnosed stomach or duodenal ulcer.
- you receive repeated blood transfusions.
- you suffer from ulcerative colitis or from any other inflammatory condition of the bowels.
- In patients who receive iron intravenously.

#### Special warnings regarding use of the medicine

##### **Before treatment with Ferro 15 inform the doctor if:**

- you are suffering or have suffered in the past from impaired function of the digestive system (such as an ulcer in the stomach or intestines, ulcerative inflammation of the colon [colitis], inflammation of the small intestine [enteritis], narrowing of the intestines, outpocketing of the inner layer of the intestine [diverticular disease])
- you are suffering or have suffered in the past from impaired function of the blood system (such as coagulation, etc.)
- you are suffering or have suffered in the past from diabetes (the preparation contains sugar) or from difficulty in absorbing certain sugars
- you are sensitive to certain sugars
- you are suffering or have suffered in the past from pernicious anemia
- your stomach has been fully or partially removed, since this condition may cause difficulties in iron absorption

##### **Additional warnings**

- Do not use this medicine frequently or for a prolonged period without consulting the doctor.
- During treatment with this medicine blood tests must be performed.
- This medicine should not be given routinely to persons with normal iron levels.
- If you are sensitive to any kind of food or medicine, inform the doctor before taking the medicine.

Accidentally swallowing an overdose of products containing iron can be life-threatening in children under 6 years of age. If a child has accidentally swallowed the medicine, immediately refer to the doctor or to an emergency room.

**If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.** Especially inform the doctor or pharmacist if you are taking:

- certain medicines for treating infections (such as: chloramphenicol, tetracyclines, quinolones: ciprofloxacin, levofloxacin, moxifloxacin, ofloxacin, norfloxacin)
- medicines containing zinc, calcium or magnesium salts
- levothyroxine for treatment of thyroid gland problems
- medicines used for treating Parkinson's disease (such as: levodopa, entacapone)
- methyl dopa for treatment of high blood pressure
- antacids for treatment of indigestion
- penicillamine for treatment of rheumatoid arthritis
- cholestyramine for reducing cholesterol and fat levels in the blood
- medicines used for bone diseases (bisphosphonates)
- trientine for treatment of high blood copper levels
- dimercaprol for treatment of different metal poisoning
- mycophenolate used in organ transplants

##### **Use of the medicine and food**

Avoid eating eggs, and drink coffee, tea or milk together with the medicine.

This medicine should be taken on an empty stomach.

In case of digestive system disorders, this medicine should be taken with or after food.

#### **Important information about some of the ingredients of the medicine**

Please note that each 5 ml of medicine contains - 500 mg dextrose, 2.5 g sucrose and less than 1.5 mg sodium. Likewise, the medicine contains the preservatives methylparaben and propylparaben.

#### 3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The dosage is according to the doctor's instructions only.

Unless otherwise instructed by the doctor, the usual dosage is generally:

For prevention - 1 mg (0.33 ml)/kg body weight per day.

For treatment - up to 2 mg (0.66 ml)/kg body weight per day.

For infants up to 2 years of age: Do not exceed a dosage of 15 mg per day.

This medicine is not intended for adults.

##### **Do not exceed the recommended dose.**

Carefully measure the dose using a measuring teaspoon or a special measuring cup.

Allow a lapse of at least two hours between taking this medicine and taking antacids, milk and milk products, antibiotics of the tetracycline group and quinolones.

Avoid eating eggs and drinking coffee, tea or milk together with this medicine.

This medicine should be taken on an empty stomach.

In case of digestive system disorders this medicine should be taken with or after food.

##### **Tests and follow up**

During treatment with this medicine blood tests must be performed.

**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 forget to take the medicine**

If you forgot to take the medicine at the required time, take the dose as soon as you remember and then continue as usual. If you remember close to the time of the next dose, do not take the missed dose.

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

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.

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

#### 4. SIDE EFFECTS

As with any medicine, use of Ferro 15 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.

##### **Stop treatment and refer to the doctor if the following occur:**

anaphylactic reaction (breathing difficulties), severe abdominal pains (rare)

##### **Refer to the doctor immediately if the following occur:**

sudden wheezing, breathing difficulties, swelling of the eyelids, face or lips, rash or itching (especially if affecting the whole body)

##### **Additional side effects:**

- abdominal discomfort
- pain in the upper abdomen
- nausea
- constipation
- diarrhea

This medicine may cause a change in the color of the urine or feces or temporarily stain the teeth. These changes should not be worrisome.

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

#### 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 use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

• Do not store at a temperature above 25°C.

• Keep tightly closed and prevent penetration of air and moisture.

• Store in the original package.

• Shelf life after first opening the bottle: one month.

#### 6. FURTHER INFORMATION

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

Methylparaben, Propylparaben, Citric Acid Anhydrous, Dextrose Monohydrate, Sucrose, Sodium Metabisulphite, Tutti Frutti, Purified Water.

**What the medicine looks like and the contents of the package:** A brown glass bottle of 120 ml capacity containing a yellowish-brown solution.

##### **Manufacturer, registration holder and address:**

Sam-On Ltd., 25 Ha'avoda St., Bat-Yam.

This leaflet was checked and approved by the Ministry of Health in July 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132-96-22885