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

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

The medicine is dispensed without a doctor's prescription

FOLIRON Tablets

Composition:

Each tablet contains: 100 mg iron (as iron III hydroxide polymaltose complex) and 0.4 mg folic acid

Inactive 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 generally intended for adults and children over 12 years of age. Below this age, use drops/syrup.

Use the medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you need further information.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for prevention and treatment of anemia caused by iron and folic acid deficiency, including during pregnancy and during lactation.

Therapeutic group: iron in combination with folic acid.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You have a known sensitivity (allergy) to the active ingredients or to any of the ingredients of the medicine (see section 6)
- You suffer from anemia unrelated to iron deficiency such as: hemolytic anemia (increased degradation of red blood cells), B12 deficiency
- You suffer from iron excess in the body
- Disorder of iron utilization by the body

Special warnings regarding use of this medicine:

Before beginning treatment, consult the doctor or pharmacist if you suffer from an infection, a tumor or B12 deficiency, or if you suffer or have previously suffered from impaired function of: the gastrointestinal system (e.g. ulcer), blood system (e.g. coagulation, etc.); in diabetics, in patients receiving repeated blood transfusions.

- Folic acid may mask B12 deficiency.
- The stool may become darker due to the use of Foliron, however, this phenomenon is harmless.

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

- Injectable iron – an addition of injectable iron is not recommended.
- Anti-epileptic medicines, especially phenytoin. Inform about commencing Foliron treatment.
- Chloramphenicol: A medicine for the treatment of bacterial infections. Administration of the medicines simultaneously may delay the effect of Foliron. Follow up is required.

Use of the medicine and food

Take the medicine during or after a meal. Before administration, this medicine can be mixed with fruit and vegetable juices or baby food.

Pregnancy and breastfeeding

No negative effect of Foliron Tablets on the unborn baby or woman has been observed during pregnancy or breastfeeding. However, if you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult the doctor or pharmacist (to adjust the dosage).

Driving and operating machinery

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

Important information about some of the ingredients in this medicine

Each Foliron tablet contains approximately 368 mg mannitol.

If you have been told by your doctor that you have an intolerance to sugar, consult your doctor before starting the treatment. Mannitol may cause diarrhea.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The recommended dosage is usually:

Adults and children over 12 years of age:

To prevent anemia: one tablet per day.

To treat anemia: 3 tablets a day in a single dose or in divided doses.

This medicine is not usually intended for babies and children (to treat babies/children, use syrup/drops).

Do not exceed the recommended dose

The medicine can be chewed or swallowed with a little water.

Attention:

Wait for at least two hours between taking this medicine and taking antacids, antibiotics from the tetracycline and quinolone groups, dimercaprol (for metal poisoning) – [waiting 24 hours is sufficient].

What is the usual duration of the treatment? It depends on the extent of the iron/folic acid deficiency.

Tests and follow up: Blood tests should be performed during the period of treatment with this medicine.

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 the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor.

Adhere to the treatment regimen recommended by 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 the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Foliron Tablets 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.

Stop using Foliron and refer to a doctor as soon as possible if the following occur: Severe abdominal pain, allergic reaction: skin rash, itching, shortness of breath.

Side effects occurring very frequently (more than 10%): Change in stool color; this change should not cause any concern. Dark stool has no clinical significance.

Side effects occurring frequently (up to 10%): Diarrhea, nausea, gastrointestinal disorders/indigestion.

Side effects occurring rarely (up to 1%): Vomiting, constipation, a change in the color of teeth, headache.

Additional side effects: Pressure in the upper part of the stomach, sensation of satiety.

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 must 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.

Do not store at a temperature exceeding 25°C.

Can be used for one month after opening.

6. FURTHER INFORMATION:

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

Mannitol, Talc, Magnesium Stearate, Sucralose

What the medicine looks like and the contents of the package:

The package contains 30 light brown tablets in a plastic jar that contains a desiccant sachet, with a child-proof latch.

License holder/Manufacturer and address: Sam-On Ltd., 25 Ehud Cinnamon (Haavoda), Bat Yam.

This leaflet was checked and approved by the Ministry of Health in: 1/2019

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 161-68-34992