PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
The medicine is dispensed without a doctor's prescription

FOROL

Tablets

Each tablet contains:
Ferrous Iron (as ferrous fumarate) 100 mg
Folic acid 400 mcg
For a list of additional ingredients in the medicine, see section 6 – Further Information.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine is not intended for children under 6 years of age. Swallow it properly. Consult the pharmacist if you need further information.

1. WHAT IS THIS MEDICINE INTENDED FOR?

The medicine is intended for prevention and treatment of iron deficiency anemia, and for maintaining the level of folic acid particularly in pregnancy.

Therapeutic group: A preparation with a combination of iron and folic acid.

2. BEFORE USING THE MEDICINE

☒ **Do not use this medicine if:**
- you have a known sensitivity to any of the ingredients of the medicine.
- you have other types of anemia that are not accompanied by iron deficiency, such as hemolytic anemia.
- you have a vitamin B12 deficiency.
- you are suffering from an impairment of the blood system.
- you are receiving or have received in the past, repeated blood transfusions.
- you are suffering from an impairment of the digestive system, such as a gastric ulcer, colitis.

Special warnings regarding use of the medicine
Do not use this medicine frequently or for a prolonged period without consulting the doctor.
During the course of treatment with this medicine, perform blood tests.
If you are sensitive to any food or medicine, especially to iron and folic acid, inform the doctor before taking this medicine.
If you are taking this medicine and your stools do not turn black, refer to the doctor.

❗ **Before treatment with Forol, inform the doctor if:**
- you are being treated, or have been treated in the past, for a gastric ulcer
- you are suffering from a folate-dependent tumor
- you have undergone surgery to fully or partially remove the stomach

❗ **If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.** In particular, inform the doctor or pharmacist if you are taking:
- antibiotics
- anticonvulsants (epilepsy)
- antacids
- penicillamines (for rheumatoid arthritis)
- sulfasalazine (for rheumatoid arthritis, intestinal diseases)
- cholestyramine (to lower cholesterol levels, for diarrhea)
- levodopa, carbidopa (for Parkinson's)
- thyroxine (for thyroid disturbances)
- bisphosphonates (for bone diseases)
- aminopterin, methotrexate (to treat different types of cancer)
- pyrimethamine (for malaria)
- trientine (for Wilson disease)
- methyldopa (for high blood pressure)
- zinc

❗ **Use of the medicine and food** Do not take this medicine with tea, coffee, milk or eggs, so that the absorption of the iron will not be affected.

❗ **Important information regarding some of the ingredients of the medicine** This preparation contains lactose and may harm people sensitive to lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.
The usual dosage is generally:
For treatment of anemia: 1-3 tablets per day.
To prevent anemia and to maintain folic acid levels: 1 tablet per day.

Do not exceed the recommended dose.

Swallow the medicine with a glass of water. Take the medicine after a meal. The tablets can be crushed.

If you took an overdose, or if a child has 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. Do not induce vomiting unless explicitly instructed to do so by the doctor.

If you forgot to take this medicine at the designated time, do not take a double dose. Take the next dose at the regular time.

How can you contribute to the success of the treatment?
Do not take medicines in the dark! Check the label and 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 Forol 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.
In addition to the desired effect of the medicine, adverse effects may occur while using it, such as: abdominal pains, constipation, diarrhea, nausea and vomiting, lack of appetite.

Discontinue use and refer to a doctor immediately if you are suffering from an allergic reaction that includes the following symptoms: breathing difficulties, swelling of the eyelids, face or lips, rash and itching.
If you are suffering from severe abdominal pains.
In any event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult with the doctor immediately.
This medicine may cause a change in the color of the stools. This change is of no concern.

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 can be reported to the Ministry of Health via the online Side Effects Report Form found on the homepage of the Ministry of Health at www.health.gov.il or via the following link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 of children and/or infants in order to avoid poisoning.
- 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.
- Storage conditions: store at a temperature up to 25°C.

6. FURTHER INFORMATION

- In addition to the active ingredients, the medicine also contains:
  Microcrystalline Cellulose, Lactose, Sodium Starch Glycolate, Povidone, Ascorbic Acid, Magnesium Stearate, Sodium Bicarbonate, Opadry OY-29020, Talc, Titanium Dioxide, Red Lake No 3.

Each tablet contains less than 1 mg sodium and approximately 75 mg lactose

- What the medicine looks like and the contents of the package – pink tablets in a blister pack
- 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 October 2015
- Registration number of the medicine in the National Drug Registry of the Ministry of Health
  154-68-34101-00