

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

Read this package insert carefully in its entirety
before using this medicine

FOLEX 400 Tablets

Composition: Active ingredients:

Each tablet contains: Ferrous Iron (as ferrous fumarate) 100 mg
Folic Acid 400 mcg

Inactive ingredients: Lactose, Ascorbic Acid, Povidone, Microcrystalline Cellulose, Sodium Starch Glycolate, Magnesium Stearate, Sodium Bicarbonate, Opadry OY-29020, Talc, Titanium Dioxide, Red Lake No. 3

Therapeutic groups: Vitamins and minerals.

Therapeutic activity: This medicine is intended for the prevention and treatment of iron and folic acid deficiency in non-pregnant women, pregnant and breastfeeding women, and in men.

When should the preparation not be used?

Do not use this medicine if you are sensitive to any of its ingredients. Do not use this medicine if you suffer from intestinal obstruction or from high iron level. Do not use this medicine in other anemic conditions not associated with iron deficiency, such as hemolytic anemia. Do not use in patients suffering from hemochromatosis - excessive absorption and accumulation of iron in body organs, or hemosiderosis - excessive deposit of iron in the body. Do not use in patients receiving iron intravenously.

Do not take this medicine without consulting a doctor before starting treatment in the following cases: If you are pregnant or breastfeeding (in order to adjust the dosage) and/or if you are suffering, or have suffered in the past, from impaired function of: the digestive system (e.g. ulcer or intestinal inflammation), the liver, the kidney/urinary tract, the blood system (e.g. malignant anemia or porphyria) and if you receive repeated blood transfusions.

Warnings: Keep this preparation out of the reach of children, in order to prevent the risk of iron overdose poisoning. Poisoning in children under 6 years of age is extremely serious. If a child has swallowed iron tablets proceed to the hospital without delay. The preparation contains lactose and may cause harm in lactose-sensitive people.

Do not use this medicine frequently, or for a long period, without consulting a doctor. During treatment with this medicine, blood tests should be performed. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: preparations containing iron, orally administered antibiotics of the tetracycline group, penicillin, chloramphenicol. Absorption of iron salts is reduced when given with antacids, zinc salts, penicillamine or cholestyramine (used to lower cholesterol). The presence of iron salts interferes with the absorption

of zinc salts, ciprofloxacin, methyldopa (for blood pressure), vitamin E. Drinking large amounts of tea prevents the absorption of iron.

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: constipation, diarrhea, nausea, abdominal pain. These effects usually disappear within a short time following the period of adaptation to the preparation. If these effects persist consult your doctor.

This medicine may cause a change in the color of the stool to a dark to black color. This change is not clinically significant.

Side effects that require special attention: If strong abdominal pain, vomiting, skin rash with irritations, shortness of breath occur (rare): discontinue treatment and contact your doctor immediately! In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately!

Recommended dosage unless otherwise prescribed by your doctor:

In pregnancy: 1 tablet a day. It is recommended to continue for up to three months following delivery.

In iron deficiency induced anemia: 1 tablet a day.

Do not exceed the recommended dosage. This medicine is not usually intended for infants and children under 12 years of age.

Attention: Allow a lapse of at least two hours between taking this medicine and taking the following medicines and products (and vice versa): antacids, milk and dairy products, calcium supplements, alcohol, tea, coffee, eggs, spinach, whole wheat bread, grains, food containing nutritive fibers, quinolones, tetracyclines (for infection), medicines for treatment of hypercalcemia (etidronate).

Directions for use: Take the medicine two hours after or one hour before a meal with a glass of water. If you experience digestive system side effects, take the medicine with or after a meal.

How can you contribute to the success of the treatment?

Complete the full course of treatment as recommended by the doctor. Even if there is an improvement in your health do not discontinue treatment without consulting the doctor.

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately 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 a doctor! **Do not take medicines in the dark!** Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: Store below 25°C. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

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