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

This medicine is dispensed without a doctor's prescription

Ferrifol Tablets

Each tablet contains:
Iron (as Iron III Hydroxide Polymaltose Complex) 100 mg and folic acid 0.4 mg.
Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and section 2 "Important information about some ingredients of the medicine".
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
Use the medicine according to the instructions in the dosage section of this leaflet.
Consult the pharmacist if you have further questions.
Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after three weeks.
The medicine is usually intended for adults and children above 12 years of age.

1. What is the medicine intended for?

The medicine is intended for prevention and treatment of anemia due to iron and folic acid deficiency, including during pregnancy and breastfeeding.
Therapeutic class: Iron in combination with folic acid.
Iron is an essential constituent of red blood cells (hemoglobin), of muscle cells (myoglobin) and of iron-containing enzymes. Folic acid is a vitamin that is important for fetal development. Folic acid deficiency in the early weeks of pregnancy may lead to fetal malformations.

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2. Before using the medicine:

☒ Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the additional components the medicine contains.
- You have an excess of iron in your body (e.g., deficiency caused by a rare disease of iron accumulation, which may lead to build-up of iron in the tissues).
- You have a problem with efficient utilization of iron (e.g., when anemia is caused by inefficient utilization of iron).
- You have anemia that is not caused by iron deficiency (e.g., anemia caused by increased hemoglobin breakdown or by vitamin B12 deficiency).

❗ Special warnings regarding the use of the medicine

Before treatment with Ferrifol Tablets, inform the doctor if:

- You have an infection or a tumor.
- You have vitamin B12 deficiency. The folic acid in this medicine may mask vitamin B12 deficiency.
- You have received blood transfusions, since there is a risk for an excess of iron due to receiving additional iron.
- You have other diseases or allergies.

❗ Tests and follow-up:

Before starting to use the medicine, the doctor will refer you for a blood test to check your blood iron and hemoglobin levels. If your symptoms are not caused by iron deficiency, this medicine will not be effective for you. During treatment with this medicine the doctor will carry out periodic examinations, and may also refer you for blood tests. This referral is normal and should not concern you.

❗ Drug-drug interactions:

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

- Injected iron preparations - using such preparations together with this medicine is not recommended.
- Medicines for treatment of epilepsy, especially phenytoin.
- Chloramphenicol - a medicine for treatment of bacterial infections. The doctor will monitor you if you are taking both of these medicines together.

❗ Use of the medicine and food:

The medicine should be taken during or after a meal.

❗ Pregnancy, breastfeeding and fertility:

No adverse effects of Ferrifol Tablets have been observed on the fetus or on women during pregnancy.
It is unknown whether iron passes into breastmilk.
If you are pregnant, planning to become pregnant or breastfeeding, consult the doctor before using the medicine.

❗ Driving and operating machinery

Ferrifol Tablets does not affect your ability to drive and/or operate machinery.

❗ Important information about some ingredients of the medicine

Each Ferrifol tablet contains 1.5 mg aspartame. Aspartame is a source of phenylalanine and may cause harm if you have phenylketonuria (a rare hereditary disorder that causes accumulation of phenylalanine, since the body cannot excrete it normally).

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.
The generally accepted dosage is:
For adults and children above 12 years of age:
For prevention of anemia: one tablet per day.
For treatment of anemia: 3 tablets per day in a single daily dose or in divided doses.
Do not exceed the recommended dose
The tablet may be chewed or swallowed whole.
How long does the treatment usually last? Depends on the extent of iron/folic acid deficiency.
If you took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of the hospital and take the package of the medicine with you.
A too high dose of folic acid may cause changes in mental state and sleep patterns, irritability and hyperactivity, nausea, abdominal bloating and flatulence.
If you have forgotten to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time.
Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Ferrifol Tablets 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.
Very common side effects - side effects that occur in more than one out of ten users:
Stool discoloration due to iron excretion. This phenomenon is harmless.
Common side effects - side effects that occur in 1-10 out of 100 users:
Nausea, constipation, diarrhea and abdominal pain.
Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
Vomiting, teeth discoloration, gastritis, itching, rash, hives, redness in the skin, headache.
Rare side effects - side effects that occur in 1-10 out of 10,000 users:
Muscle cramps and pain.
These side effects are usually transient.
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 your doctor.
Reporting side effects:
Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
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.
Store at a temperature lower than 25°C, in a dark place.

6. Additional information:

In addition to the active ingredients the medicine also contains:
Dextrates, Polyethylene Glycol 6000, Purified Talc, Aspartame, Magnesium Stearate, Chocolate Essence
What does the medicine look like and what are the contents of the package
The package contains 20 or 30 tablets in blister packs. A brown-white speckled tablet, with a chocolate aroma. Not all package sizes may be marketed.
License holder/manufacturer and the address: CTS Chemical Industries Ltd., 3 Hakidma st., Kiryat Malachi.
This leaflet was reviewed and approved by the Ministry of Health in 06/2015 and has been updated in accordance with the Ministry of Health instructions in 12/2020.
Registration number of the medicine in the national drug registry of the Ministry of Health:
131-01-30647-00