PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986 This medicine is dispensed without a doctor's prescription

Foli 5 Tablets

Composition:

Each tablet contains:

Folic acid 5 mg

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and section 2 "Important information about some of the 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. Take the product according to the instructions in the dosage section of 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 folic acid deficiency. **Therapeutic class:** folic acid and its derivatives.

2. Before using the medicine: Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (folic acid) or to any of the other ingredients this medicine contains (see section 6 "Additional information").
- You have cancer (unless you are suffering from anemia as a result of folic acid deficiency).

Special warnings regarding the use of the medicine:

The medicine should not be used without consulting a doctor before

the beginning of treatment if:

- You are being treated with hemodialysis following kidney failure.
- You have a coronary stent (a tube inserted into the artery leading to the
- heart in order to stop blockages).
 You suffer from pernicious anemia (a disorder which prevents vitamin B12 absorption) or may suffer from vitamin B12 deficiency.
- You have a tumor. Care should be taken in patients with certain tumors.
 Drug interactions

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

- Phenytoin, phenobarbital, primidone (for treatment of epileptic seizures).
- Fluorouracil (for treatment of certain types of cancer).
- Antibiotics such as trimethoprim and sulfonamides, sometimes in combination with co-trimoxazole, reduce the effect of folic acid. All antibiotics can affect the results of folic acid blood level tests.
- Medicines for indigestion (edible clay and antacids that contain aluminum or magnesium). Wait at least two hours between taking folic acid and taking medicines for indigestion.
- Zinc-containing preparations such as vitamins or food supplements (may be important in pregnancy).
- Sulfasalazine (for treatment of inflammatory bowel diseases, ulcerative colitis and Crohn's disease).
- Cholestyramine (a medicine for lowering blood cholesterol levels).

Pregnancy and breastfeeding This medicine can be taken in pregnancy for treatment of anemia. Consult with your doctor before taking the medicine if you are breastfeeding. Driving and operating machinery The medicine does not affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Foli 5 contains lactose. If you have been told by your doctor that you have intolerance to some sugars, consult your doctor before using this medicine (see also section 6 "Additional information").

3. How should you use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine. The generally accepted dosage when no other instruction from the doctor is given: one tablet per day.

Do not exceed the recommended dose.

Do not chew! The medicine should be swallowed with some water. If necessary, the tablet may be crushed. If you accidentally took an overdose or by mistake a child swallowed this medicine, go immediately to the doctor or the emergency room of a hospital and bring the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. If it is close to the time of taking the next dose, do not take the forgotten dose. Do not take a double dose in order to compensate for a forgotten dose.

Do not take medicines in the dark! Check the label and the dose <u>every</u> <u>time</u> you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, using Foli 5 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.

Seek immediate medical assistance in case of:

- Developing an allergic reaction (hypersensitivity) or a severe allergic reaction (anaphylactic reaction).
- Red/itchy skin, rash, swelling in the area of the face, lips, tongue or throat, difficulty breathing or swallowing, shock (cold skin and sweating, weak heartbeat, dry mouth, dilated pupils, dizziness, weakness and/or fainting).
 Additional side effects:
- · Lack of appetite (anorexia)
- Nausea
- · Abdominal bloating
- Flatulence
- · Worsening of vitamin B12 deficiency symptoms. Never use folic acid for treatment of anemia without fully investigating the cause of anemia. 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 the 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 below 25°C.



In addition to the active ingredient, the medicine also contains: Lactose monohydrate, Microcrystalline cellulose, Pregelatinised starch, Magnesium stearate What does the medicine look like

What does the medicine look like and what are the contents of the package?

Each Foli 5 tablet is yellow, round and convex.

Each pack contains blisters of 10 tablets. Amount of tablets in a pack: 10, 20, 30, 50, 60, 100 tablets.

Not all package sizes may be marketed. Name and address of the marketing authorization holder/manufacturer:

CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi. This leaflet was revised in 03/2024 in accordance with the Ministry of Health quidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 137-14-31322.

