

**Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986**

This medicine can be sold without a physician's prescription

FOLIC ACID

**5 mg
Tablets**

Composition:

Each tablet contains:
Folic Acid 5 mg

FOLIC ACID

**10 mg
Tablets**

Each tablet contains:
Folic Acid 10 mg

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

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

Take this medicine according to the instructions in section 3 "How to use this medicine?" in this leaflet. Consult the doctor if you need additional information.

1. What is this medicine intended for?

For the treatment of megaloblastic anemias caused by folic acid deficiency.

Therapeutic group: Folic acid and its derivatives.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (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 have anaemia due to a deficiency of folic acid).

Special warnings regarding the use of this medicine

Before using this medicine, tell the doctor if:

- You are undergoing haemodialysis due to kidney failure.
- You are receiving a coronary stent (a tube that is inserted in the artery that leads to the heart, in order to stop blockages).
- You suffer from pernicious anaemia (a disorder preventing the absorption of vitamin B12) or could be suffering from a lack of vitamin B12.
- You have a tumour. Care needs to be taken in patients with certain tumours.

Drug interactions:

If you are taking or have recently taken other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Phenytoin, phenobarbital, primidone (used to control epileptic fits).
- Fluorouracil, a drug used to treat certain tumours.
- Antibiotics. Some antibiotics like trimethoprim and sulphonamides, sometimes combined as co-trimoxazole, reduce the effect of folic acid. All antibiotics can interfere with folic acid blood test results.
- Some indigestion remedies (edible clay and antacids containing aluminium or magnesium). Allow at least a two hour gap between taking the medicine and indigestion remedies.
- Preparations containing zinc such as vitamins or food supplements (this may be important

- in pregnancy).
- Sulfasalazine, used to treat the inflammatory bowel conditions, ulcerative colitis and Crohn's disease.
 - Cholestyramine, used to reduce cholesterol levels in the blood.

Pregnancy and breastfeeding:

This medicine can be taken in pregnancy to treat anaemia.
If you are breastfeeding, please speak with your doctor before taking this medicine.

Driving and using machines:

This medicine should not affect your ability to drive a car or operate machinery.

Important information about some of the ingredients of this medicine

Folic Acid 5 mg and **Folic Acid 10 mg** contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before starting treatment with this medicine.

These medicines contain less than 1 millimole of sodium (23 mg) per tablet, that is to say it is essentially "sodium free".

3. How to use this medicine?

Always take this medicine as your doctor has told you. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

Recommended dosage unless otherwise prescribed by your doctor:
one tablet daily.

Do not exceed the recommended dose.

Method of administration:

Do not chew! Swallow the medicine with a small amount of water.
The tablet can be halved or crushed to make it easier to swallow, for immediate use.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take a dose as soon as you remember, unless it is almost time for the next dose; skip the forgotten dose and take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of folic acid 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.

Refer to medical help immediately with the appearance of:

- Allergic reaction (hypersensitivity) or a severe allergic reaction (anaphylactic reaction)

- Itchy/red skin, rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils; dizziness; weakness and/ or fainting).

Additional side effects:

- Loss of appetite (anorexia)
- Feeling sick
- Bloating of the stomach
- Flatulence (wind)
- Worsening of the symptoms of vitamin B12 deficiency. Folic acid should never be used to treat anaemia without a full investigation of the cause.

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants 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.
- Store in a dry place at a temperature below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose 100 mesh, Microcrystalline Cellulose (Avicel PH 101), Maize Starch, Ac-di-sol, Aerosil 200, Magnesium Stearate.

What the medicine looks like and what the package contains:

Round, biconvex tablets, contain orange to red granules, "R" engraved on one side.

Approved package sizes

The tablets are packed in tray packaging in boxes containing:

Folic Acid 5 mg: 30 tablets and 250 tablets.

Not all package sizes may be marketed.

Folic Acid 10 mg: 100 tablets.

Manufacturer and registration holder:

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon, Israel.

Revised in February 2024 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Folic Acid 5 mg: 128-85-21928-00

Folic Acid 10 mg: 128-86-21946-00