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

This medicines is sold without a doctor's prescription The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in 05/2014

FOLIC ACID FOLIC ACID 5 ma **Tablets Tablets**

Composition:

Each tablet contains: Each tablet contains: Folic Acid 5 mg Folic Acid 10 mg

Inactive ingredient: see the chapter 6- "Further information

Read the entire leaflet careful before you start using this medicine. This leaflet contains summary information about this medicine. If you have further questions, refer to the physician or pharmacist. Shallow this medicine correctly

1. what is this medicine intended for?

This medicine is intended for the treatment of megaloblastic anemia due to a deficiency of folic acid.

Therapeutic Group: folic acid and its derivatives

Before use this medicine:

Do not take this medicine if:

 Do not use this medicine if you have a known sensitivity to folic acid or any of ingredients of this medicine (see chapter 6)

Do not take this medicine without consulting a doctor before starting treatment:

- · If you are suffering, or have suffered in the past, from anemias of other kinds such as pernicious anemia and other megaloblastic anemias caused by vitamin B12 deficiency.

 If you are suffering from tumor.

· If you are suffering from Addison's disease and low vitamin R12 levels

Special warning concerning the medicine use: These dosages are not suitable for daily intake during childbearing age, unless otherwise directed by a doctor. Do not use this medicine frequently, or for a long period, without consulting a doctor.

If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

If you are taking or if you have just finished treatment with another medicine including medicine over the counter or dietary supplement, inform the attending doctor or pharmacist. This is especially important for medicines belonging to the following groups:

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:

· drugs used in the treatment of epilepsy (phenytoin, phenobarbital and primidone, sodium valproate carbamazepine). It is necessary to check the level in the blood of this medicines and if it is necessary to modify the dosage.

- fluorouracil (a drug used to treat certain tumours)
 certain antibiotics medicines (trimethoprim and sulphonamides)
- · Some indigestion medicines (edible clay and antacids containing aluminum or magnesium)
- Preparations contăining zinc (such as vitamins or food supplements)
- · Methotrexate (for treatment of rheumatoid arthritis or of cancer)
 Triamterene (diuretic)
- Lithium (to treat the mental health problems) · Sulfasalazine (For treatment of inflammatory bowel
- diseases or of rheumatoid arthritis)
- · Cholestyramine (used to reduce the cholesterol in blood)
- Aspirin (to treat pain and to thin your blood)
- Alcohol
- you need to breathe a gas and air mixture to put you to sleep for an operation or to relieve pain while you are awake.

Use of this medicine and food:

Do not chew! Swallow the medicine with a small amount of water.

Use of this medicine and alcohol:

Do not drink wine or alcoholic beverages while under treatment with this medicine.

Pregnancy and breast-feeding:

If you are pregnant, planning to become pregnant or are breast feeding ask your doctor for advice before taking this medicine. Folic Acid can be used during pregnancy.

Driving and using machinery:

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

Important information about some of the ingredients in Folic Acid Tablets: This medicine contains lactose and may be harmful to people who are sensitive to lactose. Do not use if you have an intolerance to some sugars.

3. How should you use the medicine?

Always use according to doctor's instructions. If you are unsure how to use this medicine, you should consult your doctor or your pharmacist

Recommended dosage unless otherwise prescribed by your doctor:

The usual dose is usually one tablet daily. Do not exceed the recommended dosage.

If you forget to take this medicine at the specified time, no need to worry, take the dose as soon as you remember, but never take a double dose at the same time.

Do not chew! Swallow the medicine with a small amount of water. The tablet may be halved or crushed.

Allow at least a two hours gap between taking Folic Acid Tablets and antiacid containing aluminum or magnesium.

Do not take this medicine with drink alcohol.

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.

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

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

4. Side Effects:

Like all medicines, folic acid use can cause side effects, although not everybody gets them. Do not be alarmed by this list of possible events. You may not have any of them. Rare side effects:

- Allergic reaction and hypersensitivity e.g. itchy/ red skin, rash, swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, shock (cold sweaty skin, weak pulse, dry mouth, dilated pupils).
- Skin rash with irritation
- · Stomach and intestines problems: loss of appetite, feeling sick, nausea, bloating, flatulence

If at any time you experience side effects that are not mentioned in this leaflet or if you feel an adverse change in your general health, consult your doctor immediately!

5. How to store this medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of reach of children and/or infants in order 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 in a dry place, at a temperature below 25°C.

Additional information:

In addition to the active ingredient the medicine also contains:

Inactive ingredients: Corn Starch, Lactose, Microcrystalline Cellulose, Croscarmellose Sodium, Magnesium Stearate, Colloidal Silicone Dioxide

Folic acid 5 mg tablet contains: 53 mg of lactose Folic acid 10 mg tablet contain: 73.8 mg of lactose

What does the medicine look like and what is the content of the package? Yellow tablets with R engraved on one side

The tablets are packaged in blister and in box of: 30 tablets, 100 tablets and 250 tablets.

Holder and manufacture: Rekah Pharmaceutical Industry Ltd. 30 Hamelacha St. Holon, Israel.

This leaflet was checked and approved in May 2014 License number: Folic Acid 5 mg: 128-85-21928-00 Folic Acid 10 mg: 128-86-2146-00

For simplicity and easier to read, this leaflet is formulated male, however, the medicine is intended for members of both sex.

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