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

The medicine is dispensed with a doctor's prescription only

LEUCOVORIN TEVA TABLETS

Composition:

Each tablet contains:

Calcium folinate 16.2 mg (equivalent to 15 mg folinic acid)

For information on inactive and allergenic ingredients in the preparation, see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

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

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Leucovorin belongs to a group of medicines called antidotes. Antidotes prevent damage caused by other substances.

Leucovorin Teva Tablets is used:

- to improve anemia conditions caused by folic acid deficiency
- to reduce the harmful effects of certain anti-cancer medicines, that are folic acid antagonists

Therapeutic group:

Formylic derivative of tetrahydrofolic acid – a metabolite of folic acid.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients contained in the medicine.
- You are suffering from anemia due to a vitamin B_{12} deficiency (malignant anemia or certain types of megaloblastic anemia).

Consult a doctor or pharmacist if you need further information.

Special warnings regarding use of the medicine

Before treatment with the medicine, tell the doctor if:

You are being treated with methotrexate. Leucovorin Teva Tablets should only be used after treatment with methotrexate.

Drug interactions

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

- Anti-epileptics (e.g., phenobarbital, phenytoin, primidone)
- Methotrexate (see section "Before treatment with the medicine, tell the doctor if")
- Antibiotics, such as chloramphenicol
- Other anti-cancer medicines, such as fluorouracil

Pregnancy and breastfeeding

Consult your doctor before taking the medicine if you are pregnant, planning to become pregnant or are breastfeeding.

Driving and operating machinery

Leucovorin Teva Tablets should not affect your ability to drive or operate machinery.

Important information about some of the ingredients of the medicine

Patients with an intolerance to **lactose** must note that leucovorin Teva tablets contain lactose. If you have been told by your doctor that you have an intolerance to certain types of sugar, talk to your doctor before taking the preparation.

Each tablet contains 194.3 mg lactose.

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 preparation dosage and treatment regimen.

There is no information regarding crushing, halving or chewing the tablet. The tablets should preferably be swallowed with a glass of water.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally:

To reduce the harmful effects of certain anti-cancer treatments:

- **Adults and children:**
  Following intravenous treatment: 15 mg (one tablet), every 6 hours, for 48 hours.

To treat anemia caused by low levels of folic acid:

- **Adults:**
  15 mg (one tablet) per day.
- **Children up to 12 years of age:**
  Your doctor will calculate the dosage appropriate for your child.

Do not exceed the recommended dose.

If you visit a different doctor or go to a hospital, inform the doctor or the attending staff about the medicines you are taking.

If you accidentally took a higher dosage than you should

If you (or someone else) swallowed many tablets of the medicine together, or if you think a child swallowed the medicine, immediately refer to a doctor or to a hospital emergency room. Please bring this leaflet, the remaining tablets and the package of the preparation to the hospital or doctor, so they will know which tablets were consumed.

If you forgot to take the medicine

If you forgot to take this medicine at the required time, take the dose as soon as you remember, unless it is time for the next dose. Do not take a double dose to compensate for the forgotten dose. Take the next dose at the usual time.

Adhere to the treatment regimen as recommended by the doctor.

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

If you have further questions regarding use of the medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Leucovorin Teva Tablets 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.

Discontinue use of the medicine and immediately refer to a doctor or closest hospital emergency room in the following case:

An allergic reaction (sudden wheezing, swelling of the lips, eyelids, face or neck leading to severe difficulty in breathing; skin rash or urticaria). This is a severe but rare side effect. You may need urgent medical attention or hospitalization.

In rare cases, fever was reported in patients receiving intravenous or intramuscular calcium folinate (Leucovorin Teva) injection before taking the tablets.

The following side effects were reported when calcium folinate (Leucovorin Teva) was given together with fluorouracil (to treat cancer):

- Reduction in the number of white blood cells or a low platelet level. Possible symptoms: skin bruises, nosebleed or rash. The doctor will refer you to blood tests to monitor these effects
- Ulcers in the oral mucosa (stomatitis) and/or diarrhea

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight 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) that appears on the package. The expiry date refers to the last day of that month.
- **Store in a dark place, below 25°C.**
- Do not discard medicines into the wastewater or waste. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

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

Lactose monohydrate, starch, pregelatinized starch, magnesium stearate.

What the medicine looks like and the contents of the package:

A round, convex, white to cream tablet with slight speckling.

The package contains 10 or 12 tablets. Not all package sizes may actually be marketed.

Name of Manufacturer and License Holder and its Address: Teva Israel Ltd.,124 Dvora Hanevi'a St., Tel Aviv 6944020.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 032.83.22115

This leaflet was revised in June 2022 according to MOH guidelines.

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