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

The medicine is dispensed with a doctor's prescription only

LEUCOVORIN TEVA TABLETS

The active ingredient and its quantity:

Each tablet contains:

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

For the list of inactive ingredients, please see section 6 "Further information".

Read this leaflet carefully in its entirety before using this 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 drugs called antidotes. Antidotes prevent the damage caused by other substances.

Leucovorin is used:

1. to improve anemia types caused by folic acid deficiency
2. to reduce the harmful effects of certain anti-cancer drugs, that are folic acid antagonists

Therapeutic group:

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

2. BEFORE USING THE MEDICINE

X 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 B12 deficiency (malignant anemia or certain types of megaloblastic anemia).

Talk to the 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 should only be used after treatment with methotrexate.

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to 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*")

! Pregnancy and breastfeeding

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

! Driving and use of machines

Leucovorin 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 tablets contain a small amount of lactose. If you have been told by your doctor that you have an intolerance to certain types of lactose, talk to your doctor before taking this 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 unsure.

There is no information regarding crushing, halving or chewing the tablet. The tablets should be swallowed (preferably 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, over a 48-hour period.

To treat anemia caused by low levels of folic acid:

- **Adults:**
  15 mg (1 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 the hospital, inform the doctor or the attending staff about the medicines you are taking.

If you accidentally took a higher dosage than necessary

If you (or someone else) swallowed many tablets 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 scheduled 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 regular 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 this medicine, consult a doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Leucovorin 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 cases:

- An allergic reaction (swelling of the lips, 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.

Rarely, fever was reported in patients receiving intravenous or intramuscular calcium folinate (leucovorin) injection before taking the tablets.

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.

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 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 in wastewater or household waste. Ask the pharmacist how to dispose of medicines no longer 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 Pharmaceutical Industries Ltd., P.O.B. 3190, Petah Tikva

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

032.83.22115

This leaflet was checked and approved by the Ministry of Health in January 2018 and was updated in accordance with the Ministry of Health guidelines in March 2019.