1. NAME OF THE MEDICINAL PRODUCT

Leucovorin Teva Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

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

Excipient with known effect: Lactose 194.3 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

A standard convex tablet, almost white to cream with slight speckling.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

To diminish the toxicity and counteract the action of folic acid antagonists such as methotrexate in cytotoxic therapy. Known as leucovorin rescue.

Amelioration of the blood picture in some megaloblastic anaemias due to folate deficiency.

4.2 Posology and method of administration

For oral administration.

Calcium Folinate Rescue:

Adults and Children: In general up to 120mg in divided doses over 12 - 24 hours by intramuscular injection, bolus intravenous injection, or intravenous infusion in 0.9% w/v sodium chloride solution followed by 12 - 15mg intramuscularly or 15mg orally, every six hours for the next 48 hours.

Leucovorin Teva should not be given simultaneously with methotrexate as it may reduce or suppress its anti-neoplastic activity. It is recommended that administration should commence within the first 24 hours following methotrexate.

In overdose situations or when the half-life of methotrexate is increased (e.g. renal function impairment or pleural or peritoneal effusions) it is important that Leucovorin Teva be given until the blood concentration of methotrexate declines to non-toxic concentrations. In these cases, doses of Leucovorin Teva equal to or greater than those of methotrexate should be given.

Folinate deficiency:

Adults: 15mg (one tablet) per day.

Children up to 12 years: 0.25mg/kg/day.

4.3 Contraindications

Known hypersensitivity to the preparation

4.4 Special warnings and precautions for use

High dose methotrexate therapy together with leucovorin rescue should only be carried out under the direction of physicians experienced in antitumour chemotherapy.

Leucovorin Teva should not be used in the treatment of pernicious anaemia or megaloblastic anaemias due to the lack of where vitamin B_{12} is deficient.

Lactose

Leucovorin Teva Tablets contains the ingredient, lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Potential interactions between folinic acid and anti-epileptics may occur; the plasma concentrations of phenobarbital, phenytoin and primidone may possibly be reduced, increasing the frequency of seizures in susceptible patients.

4.6 Pregnancy and lactation

Caution should be exercised in pregnancy and lactation

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Allergic sensitization including anaphylactoid reactions and urticaria has been reported.

Adverse reactions to calcium folinate are rare, but following intravenous or intramuscular administration, occasional pyrexial reactions have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il

4.9 Overdose
No special instructions

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
ATC Code: V03A F03 Detoxifying agents for antineoplastic treatment
Calcium Folinate is used in conjunction with methotrexate, after methotrexate therapy is stopped to reduce the toxicity of the methotrexate, it is also administered in some megaloblastic anaemia.

5.2 Pharmacokinetic properties
Calcium Folinate is readily soluble; folinic acid is absorbed by the proximal portion of the small intestine. It is rapidly distributed in tissues.

5.3 Preclinical safety data
Preclinical information has not been included because the safety profile of calcium folinate has been established after many years of clinical use. Please refer to section 4.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Lactose monohydrate
Starch
Pregelatinized starch
Magnesium stearate

6.2 Incompatibilities
Not applicable

6.3 Shelf life
The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage
Store in a dark place, below 25°C

6.5 Nature and contents of container
PVC/Aluminium blister strips in packs of 10 or 12 tablets.

6.6 Special precautions for disposal
Not applicable

7. Manufacturer & License Holder

Teva Israel Ltd.
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8. MARKETING AUTHORISATION NUMBER

032-83-22115

This leaflet was revised on January 2022 according to MOH guidelines