

Composition : Foly-5 Tablet : Each tablet contains Folinic Acid 5mg as Calcium Folate Pentahydrate BP.

Foly-15 Tablet : Each tablet contains Folinic Acid 15mg as Calcium Folate Pentahydrate BP.

Pharmacology: Folinic acid is a 5-formyl derivative of tetrahydrofolic acid. It is readily converted to other reduced folic acid derivatives (e.g., tetrahydrofolate), thus has vitamin activity equivalent to that of folic acid. Since it does not require the action of dihydrofolate reductase for its conversion, its function as a vitamin is unaffected by inhibition of this enzyme by drugs such as methotrexate. This is the classical view of folinic acid rescue therapy.

In 1980s, however, folinic acid was found to reactivate the dihydrofolate reductase itself even when methotrexate exists. Although the mechanism is not very clear, the polyglutamylation of methotrexate and dihydrofolate in malignant cells is considered to play an important role in the selective reactivation of dihydrofolate reductase by folinic acid in normal cells.

Folinic acid, therefore, allows for some purine/pyrimidine synthesis to occur in the presence of dihydrofolate reductase inhibition, so some normal DNA replication processes can proceed.

Indications : It is indicated to diminish the toxicity and counteract the effect of folic acid antagonist. To treat the Megaloblastic anemia due to folate deficiency, as in sprue, nutritional deficiency & treatment of the Megaloblastic anemia of pregnancy and infancy.

Dosage and administration : Reduction of harmful effects of folic acid antagonists such as Methotrexate, Trimethoprim etc : The dose is usually one 5-15mg tablet every 6 hours for 2 to 3 days.

Megaloblastic anemia : In the treatment of Megaloblastic anemia, the dose is one 5-15 mg tablet daily. Or, as directed by the registered physician.

Contraindication : Calcium Folate therapy is contraindicated for the following:

Known hypersensitivity to Calcium Folate, or to any components of the product formulation.

Pernicious anemia or other Megaloblastic

Foly
Calcium Folate



**DRUG
INTERNATIONAL
LTD.**

anemia where Vitamin B₁₂ is deficient.

Precaution : Calcium Folate treatment may mask pernicious anemia and other Megaloblastic anemia resulting from vitamin B₁₂ deficiency. Calcium Folate should only be used with 5-fluorouracil or Methotrexate under the direct supervision of a clinician experienced in the use of cancer chemotherapeutic agents. Many cytotoxic medicinal products- direct or indirect DNA synthesis inhibitors- lead to macrocytosis (hydroxycarbamide, cytarabine, mercaptopurine, thioguanine). Such macrocytosis should not be treated with folinic acid.

Side effects : Allergic reaction one may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing). Fits and fainting.

Use in Pregnancy and Lactation : There are no adequate and well-controlled clinical studies conducted in pregnant or breastfeeding women. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Calcium Folate is administered to a nursing mother.

Use in child : No data found.

Drug Interactions : In epileptic patients treated with Phenobarbital, Phenytoin, Primidone and Succinimides there is a risk to increase the frequency of seizures due to a decrease of plasma concentrations of anti-epileptic drug.

Overdose : There have been no reported sequelae in patients who have received significantly more Calcium Folate than the recommended dosage. However, excessive amounts of Calcium Folate may nullify the chemotherapeutic effect of folic acid antagonists.

Storage : Store below 30° C in a dry place.

Packing : Foly-5 Tablet : Each box contains 2 x 14's tablets in blister pack.

Foly-15 Tablet : Each box contains 2 x 14's tablets in blister pack.