

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

Foly Injection : Each vial (5ml) contains Folinic Acid 50mg as Calcium Folate BP.

Foly 100 Injection : Each vial (10ml) contains Folinic Acid 100mg as Calcium Folate BP.

Indications : It is indicated to diminish the toxicity and counteract the effect of impaired Methotrexate elimination, treat the Megaloblastic anemia due to folate deficiency, as in sprue, nutritional deficiency & treatment of the Megaloblastic anemia of pregnancy and infancy. Calcium Folate injection is also used in combination with 5-fluorouracil in cytotoxic therapy.

Dosage and administration : Calcium folinate should not be mixed in the same infusion as fluorouracil as a precipitate may form.

Oral-

Reduction of harmful effects of folic acid antagonists such as Methotrexate, Trimethoprimetc

: The dose is usually one 15mg tablet every 6 hours for 2 to 3 days.

Megaloblastic anemia : In the treatment of Megaloblastic anemia, the dose is one 15 mg tablet daily.

Intravenous -

Advanced Colorectal Cancer : Folinic Acid is administered at 200mg/m² by slow intravenous injection followed by 5-fluorouracil at 370 mg/m² by intravenous injection. Or 20 mg/m² by slow intravenous injection followed by 5-fluorouracil at 425 mg/m² by intravenous injection. Treatment is repeated daily for 5 days. This 5 day treatment course may be repeated at 4 weeks interval, for 2 courses and then may repeated at 4-5 weekly intervals if the patient has recovered completely from the toxic effects of the prior treatment course.

Folinic acid rescue after high dose Methotrexate Therapy : Calcium Folate starts 24 hours after the beginning of the methotrexate infusion at dose of 15mg (10mg/m²) every 6 hours for 10 doses.

Intramuscular-

Folate deficient megaloblastic anaemia : Up to 1 mg/day. Or, as directed by the registered physician.

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. Fever has been observed after administration of calcium folinate as solution for injection.

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 anemia where Vitamin B₁₂ is deficient.

Foly Injection & Tablet



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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.

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.

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.

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 : Foly Tablet : Store below 30°C away from sunlight.

Foly Injection : Store the vial in original carton at 2°C to 8°C. Do not freeze. Protect from light and keep out of the reach of the children.

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

Foly Injection : Each box contains 1 glass vial of 5 ml solution.

Foly 100 Injection : Each box contains 1 glass vial of 10 ml solution.