

# Biofol™



Folinic Acid

## Presentation

Biofol™ : Each tablet contains Calcium Folate BP eq. to Folinic Acid 15 mg.

Biofol™ 5 : Each tablet contains Calcium Folate BP eq. to Folinic Acid 5 mg.

## Description

Calcium Folate is a Calcium salt of Folinic acid (citraovorum factor), is a mixture of the diastereoisomers of the 5-formyl derivative of Tetrahydrofolic acid. It is a metabolite of Folic acid and an essential co-enzyme for nucleic acid synthesis used in cytotoxic therapy.

## Indication and Usage

Biofol is indicated-

- To diminish the toxicity and counteract the effect of impaired Methotrexate elimination
- To treat the Megaloblastic anemia due to folate deficiency, as in sprue, nutritional deficiency
- To treat the Megaloblastic anemia of pregnancy and infancy

## Dosage and Administration

a) Reduction of harmful effects of folic acid antagonists:

The dose is usually one 5-15 mg tablet every 6 hours for 2 to 3 days.

b) Megaloblastic anemia:

In the treatment of Megaloblastic anemia, the dose is one 5-15 mg tablet daily.

## 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

## 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 B<sub>12</sub> is deficient

## Precaution

- Calcium Folate treatment may mask pernicious anemia and other Megaloblastic anemia resulting from Vitamin B<sub>12</sub> 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.
- 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.

## Over dosage

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

Do not store above 30<sup>0</sup> C. Keep out of reach of children.

## Commercial Pack

Biofol™ : Each box contains 3 blister strips of 10 Tablets.

Biofol™ 5 : Each box contains 3 blister strips of 10 Tablets.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Savar, Dhaka, Bangladesh  
™ Trademark

V.N. 02  
BFL