Folic acid BP

Composition

Each 5 ml oral solution contains 2.5 mg of Folic acid BP.

Folic acid, as it is biochemically inactive, is converted to tetrahydrofolic acid and methyltetrahydrofolate by dihydrofolate reductase (DHFR). These folic acid congeners are transported across cells by receptor-mediated endocytosis where they are needed to maintain normal erythropoiesis, synthesize purine and thymidylate nucleic acids, interconvert amino acids, methylate tRNA, and generate and use formate. Using vitamin B12 as a cofactor, folic acid can normalize high homocysteine levels by remethylation of homocysteine to methionine via methionine synthetase.

Indication

- 1. Folate deficient megaloblastic anaemia
- 2. Folate deficient megaloblastic anaemia in infants
- 3. Treatment of folate deficiency in malabsorption syndromes
- 4. Megaloblastic anaemia in pregnancy
- 5. Megaloblastic anaemia associated with alcoholism
- 6.Megaloblastic anaemia associated with anti-convulsant therapy
- 7. Folic acid deficiency/megaloblastic anaemia associated with haemolytic anaemia e.g. Sickle Cell Anaemia

Dosage and administration

Route of administration: Oral

Children-Up to 1 year: 5 ml (2.5 mg) daily Over 1 year: 10 ml (5mg) to 30 ml (15 mg) daily Adults: 20 ml (10 mg) to 340 ml (20 mg) daily Or as directed by the registered physician.

Hypersensitivity to the active substance or to any of the excipients. Patients with malignant disease, unless megaloblastic anemia due to folic acid deficiency.

Warning and precaution

Folic acid should not be administered for treatment of pernicious anemia or undiagnosed megaloblastic anemia without sufficient amounts of cyanocobalamin (vitamin B12) as folic acid alone will not prevent and may precipitate development of subacute combined degeneration of the spinal cord. Therefore a full clinical diagnosis should be made before initiating treatment.

Side Effects

Folic acid is generally well tolerated.

Common side effects: Abdominal distension, flatulence

Rare side effects: Not Known

Use in Pregnancy & Lactation

Pregnancy: Folic acid deficiency during pregnancy may lead to the appearance of foetal malformations. Imbalance in folate requiring trophoblast cells may also lead to detachment of the placenta. Harmful effects in the human foetus, mother or the pregnancy have not been reported following ingestion of folic acid. Very high doses of folic acid have been shown to cause foetal abnormalities in rats.

Lactation: Folic acid is excreted in breast milk. No adverse effects have been observed in breast-fed infants whose mothers were receiving folic acid.

Use in Children and Adolescents

Folic Acid is indicated for use in infants & children.

Drug Interaction

With medicine: Absorption of folic acid may be reduced by sulfasalazine. Concurrent administration with cholestyramine may interfere with folic acid absorption. Patients on prolonged cholestyramine therapy should take folic acid 1 hour before or 4 to 6 hours after receiving cholestyramine. Antibiotics may interfere with the microbiological assay for serum and erythrocyte folic acid concentrations and may cause falsely low results. Trimethoprim or sulphonamides, alone or in combination as co-trimoxazole, may reduce the effect of folic acid and this may be serious in patients with megaloblastic anemia. Chloramphenicol may interfere with folate metabolism. Folic acid has been observed to reduce plasma levels of anticonvulsants, particularly phenytoin, phenobarbital and primidone and therefore patients should be carefully monitored by the physician and the anticonvulsant drug dose adjusted as necessary.

With food: No interaction

No cases of acute overdosage appear to have been reported, but even extremely high doses are unlikely to cause harm to patients. No special procedures or antidote are likely to be needed.

Stored below 30° C temperature and dry place, protected from light.

Keep all medicines out of reach of children.

Each amber PET bottle contains 100 ml oral solution with a measuring cup.

*Further information is available on request

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