FCIAN

Folic Acid Tablets BP 5 mg

FORM AND PRESENTATION:

Tablet of 5 mg

Box of 100: 10 blisters of 10.

COMPOSITION:

Each uncoated tablet contains:

Folic Acid	BP	5 mg
Excipients		q. s.

List of Excipients:

Microcrystalline Cellulose BP
Lactose BP
Maize Starch BP
Purified Talc BP
Magnesium Stearate BP
Colloidal Anhydrous Silica BP
Sodium Starch Glycolate BP

DESCRIPTION:

Folic acid is a component of the B group of vitamins and is necessary for the normal production and maturation of red blood cells. FCIAN is a Yellow coloured round, biconvex, uncoated tablets plain on both sides.

THERAPEUTIC INDICATION:

Folic Acid is necessary for the normal production and maturation of blood cells and is used in the treatment of nutritional megaloblastic anaemias e.g., megaloblastic anaemia following gastrectomy and the megaloblastic anaemia of pregnancy It may also be used prophylactically in chronic haemolytic states or in renal dialysis.

DOSAGE AND ADMINISTRATION:

Adults:

For nutritional megaloblastic anaemia a dose of 1 tablet daily for up to 4 months is normally sufficient but up to 15 mg daily may be required where malabsorption exists.A maintenance dose of 5 mg every 1 to 7 days may also be required

Children:

In children over 1 year the dose is as for adults.

Method of Administration:

Oral Route.

CONTRAINDICATION:

Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. In elderly people, a cobalamin absorption test should be done before long-term folate therapy. Folate given to such patients for 3 months or longer has precipitated cobalamin neuropathy. No harm results from short courses of folate.

Folic acid should never be given alone in the treatment of Addisonian pernicious anaemia and other vitamin B_{12} deficiency states because it may precipitate the onset of subacute combined degeneration of the spinal cord.

Folic acid should not be used in malignant disease unless megaloblastic anaemia owing to folate deficiency is an important complication.

Known hypersensitivity to folic acid or any of the excipients.

SPECIAL WARNING AND PRECAUTION FOR USE:

Patients with vitamin B_{12} deficiency should not be treated with folic acid unless administered with adequate amounts of hydroxocobalamin, as it can mask the condition but the subacute irreversible damage to the nervous system will continue. The deficiency can be due to undiagnosed megaloblastic anaemia including in infancy, pernicious anaemia or macrocytic anaemia of unknown aethiology or other cause of cobalamin deficiency, including lifelong vegetarians.

Caution should be exercised when administering folic acid to patients who may have folate dependent tumours.

FCIAN is not intended for healthy pregnant women where lower doses are recommended, but for pregnant women with folic acid deficiency or women at risk for the reoccurrence of neural tube defect.

FCIAN contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

There is a specific interaction between phenytoin and folate such that chronic phenytoin use produces folate deficiency. Correction of the folate deficiency reduces plasma phenytoin with potential loss of seizure control. Similar but less marked relationship exist with all anti-convulsant treatments including sodium valproate, carbamazepine and the barbiturates. Sulphasalazine and triamterene also inhibit absorption.

Antibacterials, chloramphenicol and co-trimoxazole, may interfere with folate metabolism.

Folate supplements enhance the efficacy of lithium therapy. Methotrexate and trimethoprim are specific anti-folates and the folate deficiency caused by their prolonged use cannot be treated by Folic Acid Tablets BP. Folinic acid should be used. Nitrous oxide anaesthesia may cause an acute folic acid deficiency. Both ethanol and aspirin increase folic elimination.

PREGNACY AND LACTATION:

Pregnancy:

There are no known hazards to the use of folic acid in pregnancy, supplements of folic acid are often beneficial.

Non-drug - induced folic acid deficiency, or abnormal folate metabolism, is related to the occurrence of birth defects and some neural tube defects. Interference with folic acid metabolism or folate deficiency induced by drugs such as anticonvulsants and some antineoplastics early in pregnancy results in congenital anomalies. Lack of the vitamin or its metabolites may also be responsible for some cases of spontaneous abortion and intrauterine growth retardation.

Lactation

Folic acid is actively excreted in human breast milk. Accumulation of folate in milk takes precedence over maternal folate needs. Levels of folic acid are relatively low in colostrum but as lactation proceeds, concentrations of the vitamin rise. No adverse effects have been observed in breast fed infants whose mothers were receiving folic acid.

UNDESIRABLE EFFECT:

Gastrointestinal disorders:

Rare ($\geq$1/10,000 til $<$1/1,000): Anorexia, nausea, abdominal distension and flatulence

Immune system disorders:

Rare ($\geq$1/10,000 til $<$1/1,000): Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and anaphylactic reactions (including shock).

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

No effect on concentration and co-ordination.

OVERDOSE:

There are no specific symptoms of overdosage and similarly no emergency treatment or antidotes, metabolisation and excretion can be rapid.

PRECLINICAL SAFETY DATA:

There is no pre-clinical data of relevance to a prescriber which is additional to that already included in other sections of the pack insert.

INCOMPATIBILITY:

Not Applicable

SHELF LIFE:

36 Months

STORAGE CONDITION:

Store in dry place below 30°C. Protect from light. Keep out of reach of children.

MANUFACTURED BY:

CIAN HEALTHCARE LTD.
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