

Folic Acid Tablets BP 5 mg

1. Name of the medicinal product

Folic Acid Tablets BP 5 mg TajPharma

2. Qualitative and quantitative composition

Each Uncoated Tablet Contains:
Folic Acid BP 5mg
Excipients q.s.

For excipients, see Section 6.1.

3. Pharmaceutical form

Tablet

4. Clinical particulars

4.1 Therapeutic indications

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.

4.2 Posology and method of 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. (See BNF 25).

Administration – Oral.

4.3 Contraindications

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 B₁₂ 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.

4.4 Special warnings and precautions for use

Patients with vitamin B₁₂ 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 aetiology 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.

This product 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.

Folic Acid Tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or

glucose-galactosemalabsorption should not take this medicine.

Folic Acid Tablets contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactosemalabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 Fertility, pregnancy 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.

4.7 Effects on ability to drive and use machines

No effect on concentration and co-ordination.

4.8 Undesirable effects

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 $< 1/1,000$) Not known (frequency cannot be estimated from the available data)	Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnoea, and shock. Anaphylactic reaction

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

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

5. Pharmacological properties

5.1 Pharmacodynamic properties folic acid and derivatives.

Folic acid is a member of the vitamin B group which is reduced in the body to tetrahydrofolate,

a co-enzyme active in several metabolic processes and produces a haemopoietic response in nutritional megaloblastic anaemias (but see warning in Section 4.4 regarding need for concomitant use of hydroxycobalamin).

Folic acid is rapidly absorbed and widely distributed in body tissues.

5.2 Pharmacokinetic properties

Absorption – folic acid is rapidly absorbed from the gastrointestinal tract, mainly from the proximal part of the small intestine. Dietary folates are stated to have about half the bioavailability of crystalline folic acid. The naturally occurring folate polyglutamates are largely deconjugated and reduced by dihydrofolate reductase in the intestine to form 5-methyltetrahydrofolate (5MTHF). Folic acid given therapeutically enters the portal circulation largely unchanged, since it is a poor substrate for reduction by dihydrofolate reductases.

Distribution – via portal circulation. 5MTHF from naturally occurring folate is extensively plasma bound. The principal storage site of folate is in the liver; it is also actively concentrated in the CSF. Folate is distributed into breast milk.

Metabolism – therapeutically given folic acid is converted into the metabolically active form 5MTHF in the plasma and liver. There is an enterohepatic circulation for folate.

Elimination – Folate metabolites are eliminated in the urine and folate in excess of body requirements is excreted unchanged in the urine. Folic acid is removed by haemodialysis.

5.3 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 SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose granules (*consisting of Lactose, Pregelatinised Starch and Sucrose*), Stearic acid.

6.2 Incompatibilities

None known.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC/Aluminium Blister Pack.

Pack Size: 7, 14, 28, 30, 50, 90, 100 and 500 tablets.

Not All Packs May Be Marketed.

6.6 Special precautions for disposal and other handling

Folic Acid Tablets BP 5 mg are for oral administration only.

Always read instructions on the label and the Patient Information Leaflet (PIL) enclosed.

Keep all medicines out of the reach of children.

Do not use after the expiry date.

7. Manufactured In India By:

TAJ PHARMACEUTICALS LTD.

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