

Miacil[®]

Folic Acid Tablets BP 5 mg

Composition: Each uncoated tablet contains:

Folic Acid B.P.	5 mg
Excipients	q.s.

Therapeutic indications: Folic acid is indicated for the treatment of megaloblastic anemia due to folic acid deficiency. It is also used for prophylaxis in chronic hemolytic states, during renal dialysis, and in cases of drug-induced folate deficiency.

Folic acid is used to prevent the recurrence of neural tube defects.

Dosage and method of administration:

Adults: For folate-deficiency megaloblastic anemia: 5 mg daily for 4 months.

Up to 15 mg daily may be required in cases of malabsorption.

For prophylaxis in chronic hemolytic states or during renal dialysis: 5 mg every 1–7 days, depending on diet and the underlying condition.

For drug-induced folate deficiency: 5 mg daily.

To prevent recurrence of neural tube defects: 5 mg daily before and during the first trimester of pregnancy.

Children: Over 1 year: Same as adult dose.

Up to 1 year: 500 µg/kg daily OR as directed by a physician.

Contraindications: Known hypersensitivity to folic acid. Patients with malignancy, except for megaloblastic anemia due to folic acid deficiency.

Special warnings and precautions for use: Folic acid should not be administered for the 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—the development of subacute combined degeneration of the spinal cord. Therefore, a complete clinical diagnosis must be established before initiating treatment. Folate should not be used routinely in patients receiving coronary stents. Caution should be exercised when administering folic acid to patients who may have folate-dependent tumors.

Folic acid is removed by hemodialysis.

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

Interactions with other medicines and other forms of interaction:

Folic acid absorption may be reduced by sulfasalazine.

Concomitant administration with cholestyramine may interfere with folic acid absorption.

Patients undergoing long-term treatment with cholestyramine 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 sulfonamides, alone or in combination such as co-trimoxazole, may reduce the effect of folic acid, which can be serious in patients with megaloblastic anemia.

Serum levels of anticonvulsant drugs (phenytoin, phenobarbital, primidone) may be reduced by folate administration; therefore, patients should be carefully monitored by a physician and the anticonvulsant dosage adjusted as necessary.

Fluorouracil toxicity may occur in patients taking folic acid, and this combination should be avoided. Edible clay or antacids containing aluminum or magnesium may reduce the absorption of folic acid. Patients should be advised to take antacids at least two hours after the administration of folic acid. Folic acid can reduce the intestinal absorption of zinc (of particular importance during pregnancy).

Fertility, pregnancy, and breastfeeding:

Pregnancy: Folic acid deficiency during pregnancy can lead to fetal malformations. A folate imbalance affecting trophoblast cells may also lead to placental abruption.

Very high doses of folic acid have been shown to cause fetal abnormalities in rats; however, no harmful effects on the human fetus, the mother, or the pregnancy have been reported following folic acid intake.

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

Overdose: No cases of acute overdose appear to have been reported, but even extremely high doses are unlikely to cause harm to patients. Special procedures or antidotes are unlikely to be required.

Storage: Store below 30°C in a cool, dry place. Protect from light.

Keep medicines out of the reach of children.

Presentation: Blister pack of 10 tablets.

Manufactured by:

