

ACFOL[®]
5 mg Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about ACFOL

ACFOL tablets for oral administration contain folic acid 5 mg with the following excipients: lactose monohydrate, magnesium stearate, and starch.

Folic acid is a component of the vitamin B group. It participates in several key biological processes. Deficiency in folic acid can result in megaloblastic anemia.

ACFOL is used in the treatment and prevention of the folate deficiency state.

-Acfol is indicated for the treatment of megaloblastic anemia when folate deficiency is identified as the exclusive cause. Folate deficiency is a consequence of inadequate dietary intake (as in malnutrition), malabsorption (as in sprue), or increased utilization (in conditions such as pregnancy, lactation, hemolytic anemia), increased loss (as in hemodialysis), hyperthyroidism, chronic infection or as a result of the administration of folate antagonists and other drugs that interfere with normal folate metabolism. Chronic alcohol users can become deficient in the vitamin. Certain drug may cause functional folate deficiency (such as antiepileptics, oral contraceptives, antituberculous drugs)

- Acfol is also indicated for prophylaxis of folate deficiency resulting from renal dialysis, pregnancy and lactation when the mother is malnourished and chronic hemolytic states such as thalassemia major or sickle-cell anemia.

- Acfol is indicated as a daily supplement to be taken by women planning pregnancy who are at risk of having a pregnancy affected by neural tube defects.

- Acfol supplementation significantly reduces plasma homocysteine concentrations. Elevated blood homocysteine concentrations may be an independent risk factor for atherosclerosis and ischemic heart disease. Studies indicate that individuals with a high intake of folate or vitamin B6, from vitamin supplements or food, are at lower risk of ischemic heart disease or stroke.

The way to take ACFOL

Take ACFOL as directed by your physician. Do not discontinue the treatment without consulting your doctor. Dosage and duration of treatment are individualized on the basis of the condition under treatment and the response of the patient.

Folate-deficient megaloblastic anemia due to malabsorption:

Adults:

An initial dose of 2 to 4 tablets of Acfol 5 mg daily (10 to 20 mg folic acid daily) for 14 days is recommended or until a hematopoietic response has been obtained. The daily maintenance dose is half a tablet to 2 tablets of Acfol 5 mg daily (2.5 to 10 mg daily).

Children: 1 to 3 tablets of Acfol daily (5 to 15 mg daily) according to the severity of the deficiency.

Folate-deficient megaloblastic anemia due to causes other than malabsorption:

The usual dosage is 1 tablet (5 mg) daily for 4 months.

Prophylaxis of folate deficiency:

Continued oral administration of 1 tablet (5 mg) taken daily or weekly may be necessary in chronic hemolytic cases such as thalassemia major or sickle cell anemia, depending on the diet and rate of hemolysis. Similar doses may be necessary in some patients receiving renal dialysis in order to prevent deficiency.

Expected pregnancy:

1 tablet (5 mg) taken daily for 4 weeks before conception and during the first trimester of pregnancy for women who are at risk of having pregnancy affected by neural tube defects.

In case of overdose

No reports of overdosage have been reported. Folic acid has a low acute and chronic toxicity profile. In case of intake of high doses of this medication, inform your doctor.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Known hypersensitivity to the active ingredient or any of the excipients.

Precautions

- Therapeutically acceptable doses of folic acid may be safely administered during pregnancy or lactation.
- Folic acid should never be administered for the treatment of undiagnosed megaloblastic anemia without first excluding vitamin B12 deficiency as the cause.
- The use of folic acid for the treatment of folate deficiency or for the treatment of any medical condition requires medical supervision.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

Avoid concomitant use with alcohol since chronic alcoholism decreases the absorption of folic acid.

Use with caution with phenobarbital, phenytoin and primidone.

The use of folic acid was found to enhance the antidepressant action of fluoxetine.

Adverse reactions

This drug is generally well tolerated. Gastrointestinal disturbances and hypersensitivity reactions have been rarely reported.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

ACFOL, folic acid 5 mg, pack of 50 tablets

Issue date: 12/2023

FOLT5/002

Manufactured by Mediphar Laboratories -Lebanon