FOLAC®
Tablets

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

Information about FOLAC
FOLAC is available as 0.4 mg and 1 mg tablets for oral administration.
Each tablet of FOLAC 0.4 mg contains 0.4 mg folic acid.
Each tablet of FOLAC 1 mg contains 1 mg folic acid.
Folic acid (vitamin B_9) is a member of the vitamin B group. It participates in several key biological processes.
Folic acid is crucial for proper brain function and plays an important role in mental and emotional health. It aids in the production of DNA and RNA, the body's genetic material, and is especially important during periods of high growth, such as infancy, adolescence and pregnancy. Folic acid also works closely together with vitamin B_{12} to regulate the formation of red blood cells and to help iron function properly in the body.
FOLAC can help with the following:

- *Pregnancy complications*
  - Neural tube defects

FOLAC is indicated as a daily supplement to be taken by women of child-bearing potential and pregnant women to protect against neural tube defects in their offspring.
Studies have given rise to recommendations that all women of child-bearing age who are capable of pregnancy should consume additional folic acid daily because adequate folic acid must be available very early in pregnancy, and because many pregnancies are unplanned.
There is good evidence that folic acid reduces the risk of neural tube defects, and supplementation is recommended preconceptually and during the first 12 weeks of pregnancy.
The neural tube is a structure that eventually gives rise to the central nervous system (the brain and spinal cord).
Failure of the fetal neural tube to fuse normally during the first 4 weeks of pregnancy may result in one of several congenital defects. These include anencephaly (absence of the brain and cranial vault) and spina bifida (failure of the vertebrae to fuse causing paralysis of lower body limbs).
The reasons for this failure in normal development are not well understood and appear to include both environmental and genetic factors.
It is well established that this defect is correlated with a low intake of folic acid. Pregnant women who are deficient in folic acid are more likely to have children with birth defects.

  - Other pregnancy complications

Maternal folate deficiency has also been associated with an increased risk of adverse birth outcomes, apart from neural tube defects, such as preterm delivery, low infant birth-weight, certain fetal heart defects, limb malformations, fetal growth retardation, increased incidence of miscarriage, as well as pregnancy complications like preeclampsia.
Thus, it is reasonable to maintain folic acid supplementation throughout pregnancy, even after closure of the neural tube in order to decrease the risk of other problems in pregnancy.

- *Deficiency*

The main clinical observation associated with folate deficiency is megaloblastic anemia.
FOLAC is used in the treatment and prevention of the folate deficiency state.
- FOLAC is indicated for the treatment of megaloblastic anemia when folate deficiency is identified as the exclusive cause.
- FOLAC is also indicated for prophylaxis of folate deficiency resulting from renal dialysis, pregnancy and lactation and chronic hemolytic states such as thalassemia major or sickle-cell anemia.
The main causes of folate deficiency are as follows:

- Decreased dietary intake
- Decreased intestinal absorption (e.g. coeliac disease)
- Increased requirement for folate and hence an increased risk of deficiency can occur in pregnancy, during lactation, in hemolytic anemia and leukemia, increased loss (as in hemodialysis), hyperthyroidism, chronic infection
- Alcoholism
- Drugs: Long-term use of certain drugs (e.g. antiepileptics, oral contraceptives, antituberculous drugs, sulfasalazine, trimethoprim or methotrexate) is associated with folate deficiency.
    - *Cardiovascular disease*

FOLAC 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 B_6, from vitamin supplements or food, are at lower risk of ischemic heart disease or stroke.

- Folic acid supplements may be associated with reduced risk of certain cancers.
- Poor folate status has also been demonstrated in some people with depression, dementia and Alzheimer's disease.

The way to take FOLAC

- FOLAC 0.4 mg to 1 mg daily, taken for at least one month before conception and until the third month of gestation decreases the incidence of first occurrence of neural tube defects.
It is well established that a dose of 1 mg folic acid is associated with a better prevention of neural tube defects.
Higher doses are recommended for women with a history of previous offspring with neural tube defect and for women receiving antiepileptic drugs.
- *Folate-deficient megaloblastic anemia:*
FOLAC 0.4 mg to 1 mg daily by mouth (1 tablet of FOLAC 0.4 mg or of FOLAC 1 mg daily) is suggested until a hematopoietic response has been obtained, although some patients require higher doses.
- The usual recommended dosage for reducing homocysteine levels is 0.4 mg to 1 mg daily. Higher doses are sometimes recommended.

Precautions

- This dietetic supplement is contraindicated in patients who have shown previous intolerance to folic acid.
- Therapeutically acceptable doses of folic acid may be safely administered during pregnancy or lactation.
- High doses of folic acid should never be administered for the treatment of undiagnosed anemia without first excluding vitamin B_{12} deficiency as the cause.

Associations with other medications

Please inform your doctor or pharmacist if other medicines are being taken or have been taken recently.
An adjustment and monitoring in anticonvulsant dose (phenobarbital, phenytoin and primidone) may be necessary in patients who receive supplementary folic acid.
Colestyramine may reduce the absorption of folic acid; patients on prolonged colestyramine therapy should take a folic acid supplement 1 h before colestyramine administration.

Unwanted effects

Folic acid is generally well tolerated.
Hypersensitivity reactions have been rarely reported.
Gastrointestinal disturbances have been rarely reported at very high doses.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don't use this product after this date.

Pack Presentation
FOLAC 0.4 mg, folic acid 0.4 mg, pack of 60 tablets
FOLAC 1 mg, folic acid 1 mg, pack of 30 tablets

Revision date: 02/2008