

Name of the product: Folica Plus



Each softgel capsule contains

Quatrefolic.....600 mcg
Vitamin B12..... 1000 mcg

DESCRIPTION

GENERATIONS OF FOLIC ACID

1st Generation - Food folate: Refers to the various tetrahydrofolate derivatives naturally present in foods.

2nd Generation - Folic acid:

. It is a synthetic oxidized molecule that does not occur in nature but can be utilized by the human body as a precursor to form natural folates that are biologically active.

. Folic acid lacks coenzyme activity and must be reduced to the metabolically active form within the cell, through a series of biochemical steps before it can be used by the body's cells in vital metabolic pathways such as DNA production, cell reproduction and homocysteine metabolism.

3rd Generation - (6S)-5-methyltetrahydrofolate calcium salt:

. The calcium salt of (6S)-5-methyltetrahydrofolate is available commercially and represents the third generation of folic acid. Until now, (6S)-5-methyltetrahydrofolate calcium salt was the only folic acid derivative available on the market, and able to penetrate the body cells without needing further metabolism.

4th Generation: Quatrefolic, (6S)-5-methyltetrahydrofolate glucosamine salt:

. Quatrefolic is the glucosamine salt of (6S)-5-methyltetrahydrofolate and is structurally analogous to the reduced and active form of folic acid.

. Quatrefolic represents the fourth generation folate endowed with long lasting stability as well as a peculiarly high water solubility, improved bioavailability and well established safety.

CLINICAL PHARMACOLOGY

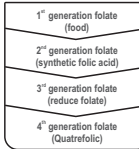
Mechanism of action

The mechanism of action of Quatrefolic is related to the action of enzyme 5-methyltetrahydrofolate, the active part of the proprietary ingredient. 5-methyltetrahydrofolate derives from tetra hydrofolic acid, through a series of metabolic reactions. Tetra hydrofolic acid acts as a coenzyme in several vital metabolic reactions participating in the transfer as acceptors and donors of various one-carbon fragments, involved in the biosynthesis of nucleotides purines and pyrimidines and in the metabolism of several important amino acids. In concert with vitamin B12, folate coenzymes allow the conversion of the amino acid homocysteine to methionine, the lack of this conversion has been associated with various pathologies and diseases.

INDICATIONS

- . During pregnancy and lactation
- . Pregnant women for prevention of neural tube defect in babies
- . As a dietary supplement in adults and older people
- . To prevent risk of spontaneous abortions
- . In hyperhomocysteinemia
- . Folate deficiency caused by some medicines (e.g. those used to treat epilepsy such as phenytoin, phenobarbital and primidone)
- . Folate deficiency caused by long-term red blood cell damage or kidney dialysis
- . In Depression, Cognitive impairment, Dementia and Alzheimer's disease

Chronology:
The generations of folate



DOSAGE AND ADMINISTRATION

The intended uses of Quatrefolic® and use levels will be same as that of folic acid, expressed on the bases of the "Recommended Dietary Allowances for Folate in Children and Adults."

AGE (Years)	MALE and FEMALES (mcg/day)	PREGNANCY (mcg/day)	LACTATION (mcg/day)
-	Folate	-	-
1 - 3	150	-	-
4 - 8	200	-	-
9 - 13	300	-	-
14 - 19	400	600	500
19+	400	600	500

HEALTH BENEFITS

Cardiovascular

Aging is associated with changes in gastrointestinal function that could possibly affect the absorption of different folate forms. This folate deficiency may be important with respect to blood formation, neurologic and cardiovascular function. It has been hypothesized that the relationship between folate deficiency and poor cognitive function may be due to the role of folate in reducing homocysteine blood and its effects on the vascular system.

Pregnancy:

Periconceptional and the first period after conception are particularly important for folate supplementation especially because a woman often does not know she is pregnant. It is recommended that for all women folate levels should be high for at least one month prior to possible conception and continued at that level for the first three months of pregnancy.

Fertility

Quatrefolic® can make a difference, bypassing folate metabolism disturbances, improving fertility, and increasing success rates in infertility treatment.

Menopause:

Homocysteine (Hcy) plasma levels are lower in women within reproductive age compared to men of the same age, although it increases after postmenopausal age, thus explaining the higher risk of cardiovascular disease documented in postmenopausal women

Cognitive:

Dietary deficiencies, Vitamin D, Magnesium, Calcium, and vitamin B are often prevalent in the elderly. Studies show that approximately 30% of individuals aged ≥ 65 years old experience a deficiency of folate. Notable works, done in healthy aging, have focused on ingredients that reduce oxidative stress (such as active folate) and consequences in health. Indeed, poor folate levels are associated with an increased risk of diseases which may imply hyperhomocysteinemia, vascular issues, and cognitive dysfunction.

Cellular health:

Due to high energy and nutrient requirements, children and adolescents are a vulnerable group for healthy growth and development. Folate is a critical nutrient when human cells growth is very active and folate deficiency can slow the overall growth rate. Infants, children, and adolescents represent a critical phase of growth and the proper level of folate is recommended to prevent a variety of medical conditions such as anemia.

Depression:

Depression is often co-occurring with a deficiency of vitamin B12, its use may be beneficial in improving the prognosis in depressed individuals. Vitamin B12 should be used as an add-on treatment to existing antidepressant treatment and/or psychotherapy rather than used as a replacement for either of these. Researchers have found that individuals with treatment resistant depression are often folate deficient.

CONTRAINDICATIONS

- . Long-term folate therapy is contraindicated in any patient with untreated cobalamin deficiency. This can be untreated pernicious anemia or other cause of cobalamin deficiency, including lifelong vegetarians.
- . Folic acid should never be given alone in the treatment of Addisonian, pernicious anemia and other vitamin B12 deficiency states because it may precipitate the onset of sub-acute combined degeneration of the spinal cord.
- . Folic acid should not be used in malignant disease unless megaloblastic anemia owing to folate deficiency is an important complication.
- . Known hypersensitivity to the active ingredient.

WARNINGS AND PRECAUTIONS

- . Caution should be exercised when administering folic acid to patients who may have folate dependent tumors.
- . 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 defects.
- . Taking folic acid supplements might make seizures worse in people with seizure disorders, particularly in high doses.
- . Pregnant or breast-feeding women shall consult health care professional before use.

ADVERSE REACTIONS

- . **Gastrointestinal disorders** Anorexia, nausea, abdominal distension and flatulence.
- . **Immune system disorders** Allergic reactions, comprising erythema, rash, pruritus, urticaria, dyspnea, and anaphylactic reactions (including shock).

DRUG INTERACTIONS

- . **Fosphenytoin** Folic acid along with fosphenytoin might decrease the effectiveness of fosphenytoin for preventing seizures.
- . **Methotrexate** Folic acid along with methotrexate might decrease the effectiveness of methotrexate.
- . **Phenobarbital** Folic acid can decrease the phenobarbital effect for preventing seizures.
- . **Phenytoin** Folic acid along with phenytoin might decrease the effectiveness of phenytoin and increase the possibility of seizures.
- . **Primidone** Folic acid along with primidone might decrease how well primidone works for preventing seizures.

Pyrimethamine

Folic acid might decrease the effectiveness of pyrimethamine for treating parasite infections.

Sulfasalazine can reduce the absorption of folic acid.

USE IN SPECIAL POPULATIONS

Pregnancy

US FDA Pregnancy Category A. Folic acid is likely safe when taken by mouth appropriately during pregnancy. Folic acid combined with Vit B12 can help prevent spinal and nervous system birth defects in baby.

Nursing mothers Folic acid is actively excreted into human milk. No adverse effects in nursing infants have been associated with the use of folic acid during lactation.

STORAGE AND PRECAUTIONS:

Avoid direct sunlight and protect from heat and moisture. Store Below 25 °C. Keep all medicines out of the reach of children.

PRESENTATION: Folica plus Softgel capsules are available in packaging of Plastic jar containing 30 softgel capsules.

عمومی خوراک: فوٹا کی ہدایت کے مطابق۔

احتیاط: دوا صرف مستند ڈاکٹر کے زیر ہدایت استعمال کریں۔ دھوپ، نمی اور گرمی سے بچائیں۔ 25 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر محفوظ کریں۔ تمام ادویات بیچوں کی پہنچ سے دور رکھیں۔



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یوزر سے نیچل: کسی بیماری کے علاج کیلئے نہیں ہے

SRO 412 (1) / 2014 Enlisted Product