Adfolic® Quatrefolic®
Adfolic® Quatrefolic® OD

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SUPPLEMENT FACTS

Adfolic Tablet:
Each tablet contains: Folate [Quatrefolic® 600mcg as (6S)-5-MTHF, glucosamine salt] (Vegetarian Source)SP……..300mcg

Adfolic OD Tablet:
Each tablet contains: Folate [Quatrefolic® 1200mcg as (6S)-5-MTHF, glucosamine salt] (Vegetarian Source)SP……..600mcg
(PharmEvo Specs.)

DESCRIPTION

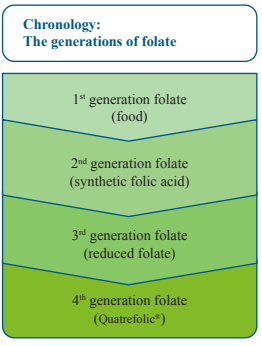
GENERATIONS OF FOLIC ACID

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 5-methyltetrahydrofolate, the active part of the proprietary ingredient. 5-methyltetrahydrofolate derives from tetrahydrofolic acid, through a series of metabolic reactions. Tetrahydrofolic 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 concern 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. Conversion of tetrahydrofolic acid to 5-methyltetrahydrofolate is mediated by the action of the enzyme methylenetetrahydrofolate reductase. Supplementation with 5-methyltetrahydrofolate might be preferable to folic acid, being it is immediately available to react with homocysteine to avoid the possibility of hyperhomocysteinaemia.

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

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)	MALES AND FEMALES (mcg/day)	PREGNANCY(mcg/day)	LACTATION(mcg/day)
-	Folate	-	-
1-3	150	-	-
4-8	200	-	-
9-13	300	-	-
14-18	400	600	500
19+	400	600	500

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. 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 has occurred from short courses of folate
• 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
• 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 sub-acute irreversible damage to the nervous system will continue. The deficiency can be due to undiagnosed megaloblastic anemia including in infancy, pernicious anemia or macrocytic anemia of unknown etiology or other cause of cobalamin deficiency, including lifelong vegetarians.
• 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.
• Please consult your pharmacist/doctor before taking this product.

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
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. Taking 600 mcg of folic acid daily is commonly used during pregnancy to prevent birth defects and some neural tube defects.
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.

OVERDOSE & TREATMENT:
No information available regarding the overdose of Quatrefolic®. However for folic acid, no special procedures or antidote are likely to be needed.

PRESENTATION
Adfolic 300mcg: Box of 30 Tablets
Adfolic OD 600mcg: Box of 30 Tablets

INSTRUCTIONS
Store below 30°C.
Protect from sunlight, heat and moisture.
Keep out of the reach of children.

ہدایات:
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔

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DRAP Product Enlistment Number : Adfolic® 300mcg:
DRAP Product Enlistment Number : Adfolic® OD 600mcg:

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