Elfolate™ and Elfolate Plus™ tablets (L-METHYLFOLATE CALCIUM as Extrafolate-S®)

Aventura Pharmaceuticals, LLC

DESCRIPTION

Elfolate™ and Elfolate Plus™ tablets is an orally administered medical food for patients requiring increased folate levels.

Elfolate™ and Elfolate Plus™ tablets should be administered under the supervision of a medical professional.

Each tablet contains L-Methylfolate Calcium as Extrafolate-S®.

Other ingredients:

15mg - calcium phosphate dibasic dihydrate, microcrystalline cellulose, stearic acid, Opadry II Green, magnesium stearate

7.5mg - calcium phosphate dibasic dihydrate, microcrystalline cellulose, stearic acid, Opadry II blue, magnesium stearate

3mg – Pyridoxal 5' Phosphate 35mg, Methylcobalamin 2mg, calcium phosphate dibasic dihydrate, microcrystalline cellulose, stearic acid, Opadry II White, magnesium stearate

FOLATE REGULATION

The term "folate" are B vitamins that include folic acid and any forms of active pteroylglutamates regardless of the reduction state of the molecule. Folates, or vitamin B_9, are primarily hydrolyzed in the intestinal jejunum and the liver to the active circulating form of folate, l-methylfolate, with an intermediate stable form, 5,10-methylenetetrahydrofolate.

Individuals with genetic polymorphisms for the genes coding methylenetetrahydrofolate reductase (MTHFR) may not be capable of utilizing or metabolizing folic acid adequately for the vitamin B_{12} dependent methylation cycle.

INDICATIONS AND USAGE

Elfolate™ and Elfolate Plus™ is indicated for the distinct nutritional requirements of patients in need of dietary supplementation as determined by a medical professional. Elfolate™ and Elfolate Plus™ should be administered under the supervision of a medical professional.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNINGS

Caution is recommended in patients with a history of bipolar illness.

PRECAUTIONS

General

Folate, when administered as a single agent in doses about 0.1 mg daily, may obscure the detection of vitamin B_{12} deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B_{12} deficiency, including pernicious anemia, while not addressing the neurological manifestations). Folate therapy alone is inadequate for treatment of a vitamin B_{12} deficiency.

A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed, (although not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of a precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Caution is recommended in patients with a history of bipolar illness.

Patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder since mood elevation in this population is possible.

DRUG INTERACTIONS

Drugs which may interact with folate include:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, fosphenytoin, valproate, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate.
- Additionally, concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the level of the AED in the blood and allowing breakthrough seizures to occur. Caution should be used when prescribing this product among patients who are receiving treatment with phenytoin and other anticonvulsants.
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.
- Cholestyramine: Reduces folic acid absorption and reduces serum folate levels.
- Colestipol: Reduces folic acid absorption and reduces serum folate levels.
- Cycloserine: Reduces folic acid absorption and reduces serum folate levels.
- Dihydrofolate Reductase Inhibitors (DHFRI): DHFRIs block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFRIs include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.
- L-dopa, triamterene, colchicine, and trimethoprim may decrease plasma folate levels.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs have been shown to inhibit some folate dependent enzymes in laboratory experiments. NSAIDs include ibuprofen, naproxen, indomethacin and sulindac.
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.
- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts, such as pancreatin and pancrelipase.
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.
- Pyrimethamine: High levels of folic acid may result in decreased serum levels of pyrimethamine.
- Smoking and Alcohol: Reduced serum folate levels have been noted.
- Sulfasalazine: Inhibits the absorption and metabolism of folic acid.
- Metformin treatment in patients with type 2 diabetes decreases serum folate.
- Warfarin can produce significant impairment in folate status after a 6-month therapy.
- Folinic acid may enhance the toxicity of fluorouracil.
- Concurrent administration of chloramphenicol and folinic acid in folate-deficient patients may result in antagonism of the haematopoietic response to folate.
- Caution should be exercised with the concomitant use of folinic acid and trimethoprim-sulfamethoxazole for the acute treatment of *Pneumocystis carinii* pneumonia in patients with HIV infection as it is associated with increased rates of treatment failure and mortality in a placebo controlled study.

PREGNANCY and NURSING MOTHERS

Elfolate™ and Elfolate Plus™ is not intended for use as a prenatal/postnatal multivitamin for lactating and non-lactating mothers. This product contains a B vitamin in reduced form. Talk with your medical professional before using if pregnant or lactating.

ADVERSE REACTIONS

Allergic reactions have been reported following both oral and parental administration of folic acid, and may possibly occur with other forms of folate.

DOSAGE AND ADMINISTRATION

Take 1 tablet two (2) times daily with or without food, or as directed by a medical professional.

HOW SUPPLIED

Elfolate™ Tablets 15mg are coated, light green, oval, and are supplied in bottles of 90 tablets.

ID# 69206-120-90 (90 ct. bottle / 90 tablets)

Elfolate™ Tablets 7.5mg are coated, light blue, round, and are supplied in bottles of 30 and 90 tablets.

ID# 69206-110-30 (30ct. bottle / 30 tablets)

ID# 69206-110-90 (90 ct. bottle / 90 tablets)

Elfolate Plus™ Tablets 3mg are coated, white, round, and are supplied in bottles of 90 tablets.

ID# 69206-230-90 (90 ct. bottle / 90 tablets)

STORAGE

Store at controlled room temperature 15°-30°C (59°-86°F). Protect from heat, light and moisture.

KEEP THIS OUT OF REACH OF CHILDREN.

Call your medical professional about any side effects

you may be experiencing. You may report side effects

by calling 516-405-3790

Manufactured for:
Aventura Pharmaceuticals, LLC
4400 Route 9 South
Suite 1000
Freehold, NJ 07728
www.aventurapharma.com
MADE IN USA

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