METHAZEL- methazel capsule
Sterling-Knight Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Methazel
Capsules

Rx Only

DESCRIPTION

Methazel is an orally administered prescription dietary supplement specifically formulated for the dietary management of patients with unique nutritional needs requiring increased folate levels as well as other supplementation.

Methazel should be administered under the supervision o f a licensed medical practitioner. Each capsule contains the following ingredients:

Each capsule contains:

Folic Acid.....1mg
Pyriodoxal 5 Phosphate.....,.....50mg
Methylcobalamin.....2.5mg
CoQ10.....25mg
Alpha Lipoic Acid 50mg
N-Acetylcysteine.....50mg

Each capsule contains the following inactive ingredients: Soybean Oil, Gelatin (Bovine), Bees wax, Yellow, Glycerin, Deionized Water, Lecithin, Titanium Dioxide, FD&C Blue #1, FD&C Red #40.

* This product is a prescription vitamin that – due to increased folate levels (AUG 2 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B12 deficiency. As such, this product requires licensed medical supervision, an Rx status, and a National Drug Code (NDC) as required by pedigree reporting requirements.

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 B9, are primarily hydrolyzed in the intestinal jejunum and the liver to the active circulating form of folate.

Folic acid, including reduced forms1 such as folinic acid, may obscure pernicious anemia above 0 .1 mg doses, and must be administered under the supervision o f a licensed medical practitioner.

INDICATIONS & USAGE

Methazel is indicated for the distinct nutritional requirements of patients in need of dietary supplementation as determined by a licensed medical practitioner. Methazel should be administered under the supervision o f a licensed medical practitioner.

PATIENT MEDICATION INFORMATION

Methazel is a prescription dietary supplement to be used only under licensed medical supervision.

DRUG INTERACTIONS

Drugs which may interact with folate include:

- Antiepileptic drug s (AED): The AED class including , but not limited to , phenytoin, carbamazepine, primidone, valproic acid, fosphenytoin, valproate, phenobarbital and lamotrigine have been shown to impair fo late absorption and increase the metabolism of circulating fo late.
- 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 pro duct among patients who are receiving treatment with phenytoin and other anticonvulsants.
- Cholestyramine: Reduces folic acid absorption and reduces serum folate levels.
- Colestipo l: Reduces folic acid absorption and reduces serum folate levels.
- Cyclo serine: 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 Drug s (NSAIDs): NSAIDs have been shown to inhibit so me 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 Alco ho l: 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 product significant impairment in folate status after a 6-mo nth 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 haemato poietic response to folate.
- Caution should be exercised with the concomitant use of folinic acid and trimethoprim-sulfamethoxazole for the acute treatment of Pneumocystis cariniipneumonia in patients with HIV infection as it is associated with increased rates of treatment failure and mortality in a placebo controlled study.

Drugs which may interact with vitamin B : 12

- Antibiotic, cholestyramine, colchicines, colestipol, metformin, para-amino salicylic acid, and potassium chloride may decrease the absorption of vitamin B12.
- Nitro us oxide can produce a functional vitamin B12 deficiency.

Drug s which interact with vitamin B6:

- Vitamin B6 should not be given to patients receiving the drug levodopa because the action of levodopa is antagonized by vitamin B6. However, vitamin B6 may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

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

Folic acid when administered as a single agent in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. The 2 mgs of B12 (cyanocobalamin), the amount contained in Methazel, has been shown to provide an adequate amount of B12 to address this precaution. Unmetabolized folic acid has been shown in one study of 105 postmenopausal women (50-75 yrs) to have the potential to reduce natural killer cells' cytotoxicity, which may result in an impaired immune response.

B12 should not be used in those with Leber's optic atrophy. Decreased levels of B have been associated with reduced ability to detoxify the cyanide in exposed individuals and B may increase the risk of irreversible neurological damage from optic atrophy in those affected with the disorder. Hydroxocobalamin can aid in the detoxification of cyanide. This form of B12, although not in this product, is an acceptable form for >B12 supplementation in those with this disorder.

Caution should be exercised when Methazel is administered to patients with diabetic nephropathy. One published study showed that among patients with diabetic nephropathy given high dose folic acid, vitamin B12, and vitamin B (pyridoxine) versus a placebo, there was a greater decrease in glomerular filtration rate (GRF).

Pregnant women and nursing mothers may be recommended to use 12 microgram doses of B12 from nutritional supplements, although higher doses should only be taken on the recommendations of a prescribing medical professional. Administration of doses of vitamin B12 greater than 10 micrograms daily may produce a hematological response in those with anemia secondary to folate deficiency.

Folate, when administered as a sing le agent in doses about 0.1 mg daily, may obscure the detection of vitamin B12 deficiency (specifically, the administration of folic acid may reverse the hematological manifestations of B12 deficiency, including pernicious anemia, while not addressing the neurological manifestations).

Folate therapy alone is inadequate for treatment o f a vitamin B12 deficiency.

PREGNANCY

Methazel is not intended for use as a prenatal/postnatal multivitamin for lactating and no n- lactating mother. T his pro duct contains B vitamins in active form. Talk with your medical practitioner before using if pregnant or lactating.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parental administration of folic acid, and may possibly occur with other forms of folate. Paresthesia, somnlence, nausea and headaches have been reported with vitamin B6. Mild transient diarrhea, polycythemiavera, itching, transitory exanthema

and the feeling of swelling of the entire body have been associated with vitamin B12.

DOSAGE & ADMINISTRATION

One capsule daily or as directed by a licensed medical practitioner. Methazel capsules are supplied as purple capsules printed with 350 dispensed in HDPE plastic bottles of 30ct.

NDC 69336-350-30

STORAGE AND HANDLING

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

PACKAGE LABEL

KEEP THIS OUT OF T HE REACH OF CHILDREN.

Rx Only

Reserved for Professional Recommendation
All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:
Sterling-Knight Pharmaceuticals, LLC
Ripley, MS 38663

MADE IN USA Rev. 10/2015

METHAZEL

methazel capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69336-350
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
PYRIDOXAL 5-PHOSPHATE (UNII: F06SGE49M6) (PYRIDOXAL 5-PHOSPHATE - UNII:F06SGE49M6)	PYRIDOXAL 5-PHOSPHATE	50 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	2.5 mg
COENZYME Q10, (2Z)- (UNII: U705VLF0VW) (COENZYME Q10, (2Z)- - UNII:U705VLF0VW)	COENZYME Q10, (2Z)-	25 mg
ALPHA LIPOIC ACID (UNII: 73Y7P0K73Y) (.ALPHA.-LIPOIC ACID - UNII:73Y7P0K73Y)	ALPHA LIPOIC ACID	50 mg
ACETYLCYSTEINE (UNII: WYQ7N0BPYC) (ACETYLCYSTEINE - UNII:WYQ7N0BPYC)	ACETYLCYSTEINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
SOYBEAN OIL (UNII: 241ATL177A)	
GELATIN (UNII: 2G86QN327L)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	purple	**Score**	no score
Shape	capsule	**Size**	22mm
Flavor		**Imprint Code**	350
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69336-350-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/12/2015	

Labeler - Sterling-Knight Pharmaceuticals, LLC (079556942)