DEPLIN® 7.5mg Tablets
DEPLIN® 15mg Caplets

DESCRIPTION

DEPLIN® is a medical food dispensed by prescription for the clinical dietary management of the metabolic imbalances associated with depression and schizophrenia. Use under medical supervision.

Each DEPLIN® 7.5mg tablet contains 7.5 mg of L-methylfolate (Metafolin®)*. *CAS#151533-22-1
Each DEPLIN® 15mg caplet contains 15mg of L-methylfolate (Metafolin®)*. *CAS#151533-22-1

DEPLIN®-7.5mg Dietary Ingredients:
Dibasic Calcium Phosphate Dihydrate, Silicified Microcrystalline Cellulose 90, Silicified Microcrystalline Cellulose HD 90, Opadry II Blue 85F90748 (Polyvinyl Alcohol, Titanium Dioxide [color], PEG 3350, Talc and FD&C Blue #2[color]), L-methylfolate Calcium, Magnesium Stearate (Vegetable Source), and Carnauba Wax.
DEPLIN® 7.5mg tablets do not contain sugar, lactose, yeast or gluten.

DEPLIN®-15mg Dietary Ingredients:
Dibasic Calcium Phosphate Dihydrate, Silicified Microcrystalline Cellulose 90, Opadry II Orange 85F43102, (Polyvinyl Alcohol, Titanium Dioxide [color], PEG 3350, Talc, FD&C Yellow #6[color], FD&C Yellow #5[color], FD&C Red #40[color] and FD&C Blue #2[color]), L-methylfolate Calcium, Magnesium Stearate (Vegetable Source), and Carnauba Wax.
DEPLIN® 15mg caplets do not contain sugar, lactose, yeast or gluten.

Medical foods are intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.[1] This product is not an Orange Book product.

DEPLIN® is a medical food dispensed by prescription.

CLINICAL PHARMACOLOGY

DEPLIN® is a medical food, which consists of a proprietary biologically active folate, derived from food sources.

INDICATIONS AND USAGE

ADJUNCTIVE USE IN MAJOR DEPRESSIVE DISORDER

DEPLIN® is indicated for the distinct nutritional requirements of individuals who have suboptimal L-methylfolate levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD) with particular emphasis as adjunctive support for individuals who are on an antidepressant.[2-5]

ADJUNCTIVE USE IN SCHIZOPHRENIA

DEPLIN® is indicated for the distinct nutritional requirements of individuals who have or are at risk for hyperhomocysteinemia and have schizophrenia who present with negative symptoms and/or cognitive impairment, with particular emphasis as an adjunctive support for individuals who have stabilized on antipsychotics.[2]

DEPLIN® is indicated regardless of MTHFR C677T polymorphism genotype.[6]

CONTRAINDICATIONS

DEPLIN® is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PRECAUTIONS

General:
Folic acid, when administered in daily doses above 0.1mg, may obscure the detection of 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). L-methylfolate may be less likely than folic acid to mask vitamin B_{12} deficiency.[7,8] Folate therapy alone is inadequate for the treatment of a 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. DEPLIN® is not an antidepressant; however, 5-MTHF has been shown to enhance antidepressant effects of known antidepressants.[2] 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.

Patient Information:
DEPLIN® is a medical food[1] for use under medical supervision and direction.
DEPLIN® is a medical food dispensed by prescription.

Interaction with Drugs:
Before using this product, tell your doctor or pharmacist of all the products you use. Keep a list of all your medications with you, and share the list with your doctor and pharmacist. No decrease in effectiveness of drugs has been reported with the use of DEPLIN®.

DEPLIN® contains folate, which may have interactions the following:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, 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 this AED in the blood and allowing breakthrough seizures to occur.[9,10,12,15]
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.[11]
- Dihydrofolate Reductase Inhibitors (DHFRI): DHFIs block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFIs include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.[12]
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.[13]
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin,[14]
- 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.[12]
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.[12]
- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylpredinisolone.[12]
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts.[12]
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.[12]
- Metformin treatment in patients with type 2 diabetes decreases serum folate.[16,17]
- Warfarin can produce significant impairment in folate status after a 6-month therapy.[18]

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate.

DOSAGE AND ADMINISTRATION

The usual adult dose is 7.5mg to 15mg given daily with or without food or as directed under medical supervision.

HOW SUPPLIED

DEPLIN® is a medical food dispensed by prescription

7.5mg Bottle of 30 Product Code # 0525-0410-30*
Use under medical/physician supervision.

Bottle of 90 Product Code # 0525-0410-90*
Use under medical/physician supervision.

Bottle of 7 Product Code # 0525-0410-07*
Professional samples. Not for sale.

A light blue, round, coated, tablet imprinted on one side with “PAL” and imprinted on the other side with “7.5”.

15mg Bottle of 90 Product Code # 0525-0450-90*
Use under medical/physician supervision.

Bottle of 7 Product Code # 0525-0450-07*
Professional samples. Not for sale.

An orange, oval, coated, caplet imprinted on one side with “deplin” and imprinted on the other side with “15”.

*Pamlab LLC does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirements of pharmacy and health insurance computer systems.

Storage:
Store at controlled room temperature 15°C to 30°C (59°F to 86°F) (See USP). Protect from heat, light and moisture.

PATENTS

Some or all of the following patents may apply:
U.S. Patent No. 6,011,040
U.S. Patent No. 6,441,168B1
and other pending patent applications

REFERENCES

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