

CerefolinNAC[®] Caplets

DESCRIPTION

CerefolinNAC[®] is a medical food dispensed by prescription (Rx) for the clinical dietary management of the metabolic imbalances associated with mild or moderate cognitive impairment. Use under medical supervision.

Each caplet contains: 6mg of L-methylfolate Calcium (as Metafolin[®])* and 90.314mg of Algae-S Powder (*Schizochytrium*), 2mg of Methylcobalamin and 600mg of N-Acetyl-L-Cysteine. *CAS#151533-22-1

Dietary Ingredients:

N-acetyl-L-Cysteine, Silicified Microcrystalline Cellulose NF, Algae-S Powder (*Schizochytrium* Algal Oil [Vegetable source], Glucose Syrup Solids, Mannitol, Sodium Caseinate (milk), Soy Protein, High Oleic Sunflower Oil, 2% or less Sodium Ascorbate, Tricalcium Phosphate, Tetrasodium Diphosphate, Natural Flavors, Soy Lecithin, and Mixed Natural Tocopherols and Ascorbyl Palmitate [as antioxidants]), Polyvinyl Alcohol, Croscarmellose Sodium NF, Titanium Dioxide, Polyethylene Glycol 3350, L-methylfolate Calcium (Metafolin[®]), Magnesium Stearate (NF, Vegetable Source), Talc, Methylcobalamin, Beet Powder Red (color), Caramel FCC (color), Carnauba Wax. **Contains Milk and Soy.**

CerefolinNAC[®] caplets do not contain lactose, yeast or gluten.

CerefolinNAC[®] is a medical food dispensed by prescription (Rx) under medical supervision and direction.

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.

INDICATIONS AND USAGE

CerefolinNAC[®] is indicated for the distinct nutritional requirements of individuals with mild to moderate cognitive impairment who present with an increased risk for neurovascular oxidative stress²⁻¹ and/or hyperhomocysteinemia⁸⁻¹⁶; and/or suboptimal L-methylfolate and/or vitamin B12 levels in the cerebrospinal fluid, plasma, and/or red blood cells⁸⁻²¹.

CONTRAINDICATIONS

CerefolinNAC[®] 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 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). L-methylfolate Calcium may be less likely than folic acid to mask vitamin B₁₂ deficiency.²²⁻²³ Folate therapy alone is inadequate for the treatment of a B₁₂ deficiency.

N-acetyl-L-cysteine should be avoided by nursing mothers.²⁴ N-acetyl-L-cysteine clearance is reduced in those with chronic liver disease as well as in pre-term newborns.²⁴ Headaches may be intensified in those taking N-acetyl-L-cysteine and nitrates for the treatment of angina.²⁴ While the incidence of renal stones is low, those that do form renal stones, particularly cysteine stones should avoid CerefolinNAC[®].²⁴ Do not administer CerefolinNAC[®] to critically ill patients.²⁴ N-acetyl-L-cysteine and its sulfhydryl metabolites could produce a false-positive result in the nitroprusside test for ketone bodies used in diabetes.²⁴ N-acetyl-L-cysteine should be used with caution in those with a history of peptic ulcer disease since N-acetyl-L-cysteine may disrupt the gastric mucosal barrier.²⁴

Patient Information:

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ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.²⁵ Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with methylcobalamin.²⁶ Nausea, vomiting, diarrhea, transient skin rash, flushing, epigastric pain, and constipation have been associated with N-acetyl-L-cysteine.²⁴

DOSAGE AND ADMINISTRATION

The usual adult dose is one caplet daily or as directed under medical supervision.

HOW SUPPLIED

CerefolinNAC[®] is a medical food dispensed by prescription (Rx) under medical supervision and direction.

Available as an oval coated beige colored caplet. Debossed with "PAL" on one side and "600" on the other.

Commercial Product (90 caplets)
Sample Product Blisters (6 caplets)

0525-0555-90*
0525-0555-06*

Use under medical/physician supervision.
Professional Samples – Not for sale.

*Pamlab LLC does not represent these product codes to be a 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.

MERCK EXHIBIT 2076

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PATENTS

Some or all of the following patents may apply:

U.S. Patent No. 5,997,915
U.S. Patent No. 6,008,221
U.S. Patent No. 6,011,040
U.S. Patent No. 6,127,370
U.S. Patent No. 6,254,904
U.S. Patent No. 6,441,168B1
U.S. Patent No. 7,172,778
U.S. Patent No. 7,674,490
U.S. Patent No. 7,709,460B2

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26. Natural Standard Research Collaboration (NIH). *Vitamin B12 Monograph* 2009

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