

## CerefolinNAC® Caplet

A medical food for the dietary management of mild cognitive impairment.

### DESCRIPTION

Each beige coated caplet contains:

#### Dietary Ingredients:

|                                     |           |
|-------------------------------------|-----------|
| L-methylfolate Calcium (Metafolin®) | 6 mg      |
| Algae-S Powder (Schizochytrium)     | 90.314 mg |
| Methylcobalamin                     | 2 mg      |
| N-Acetyl-L-Cysteine                 | 600 mg    |

#### Other Ingredients:

N-Acetyl 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, Natural Flavors, Tricalcium Phosphate, Tetrasodium Diphosphate, Tocopherols, Soy Lecithin, and Ascorbyl Palmitate (as antioxidants), Opadry II Beige 85F170035 (Polyvinyl Alcohol, Titanium Dioxide, PEG 3350, Talc, Beet Powder, Caramel), Croscarmellose Sodium, Magnesium Stearate (NF, Vegetable Source), L-methylfolate Calcium, Methylcobalamin, Carnauba Wax

**Contains Milk and Soy**

**CerefolinNAC® Caplets are Gluten Free**

### 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 stress and/or hyperhomocysteinemia; and/or suboptimal L-methylfolate and/or vitamin B12 levels in the cerebrospinal fluid, plasma, and/or red blood cells.<sup>1-20</sup>

### PRECAUTIONS

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.<sup>21-22</sup> Folate therapy alone is inadequate for the treatment of a B12 deficiency. N-acetyl-L-cysteine should be avoided by nursing mothers.<sup>23</sup> N-acetyl-L-cysteine clearance is reduced in those with chronic liver disease as well as in pre-term newborns.<sup>23</sup> Headaches may be intensified in those taking N-acetyl-L-cysteine and nitrates for the treatment of angina.<sup>23</sup> While the incidence of renal stones is low, those that do form renal stones, particularly cysteine stones should avoid CerefolinNAC®.<sup>23</sup> Do not administer CerefolinNAC® to critically ill patients.<sup>23</sup> N-acetyl-L-cysteine and its sulfhydryl metabolites could produce a false-positive result in the nitroprusside test for ketone bodies used in diabetes.<sup>23</sup> 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.<sup>23</sup>

### ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral L-methylfolate Calcium.<sup>24</sup> Mild transient diarrhea, itching, transitory exanthema, and the feeling of swelling of the entire body has been associated with methylcobalamin.<sup>25</sup> Nausea, vomiting, diarrhea, transient skin rash, flushing, epigastric pain, and constipation have been associated with N-acetyl-L-cysteine.<sup>23</sup>

### CONTRAINDICATIONS

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

### PATIENT INFORMATION

CerefolinNAC® is a medical food for use under medical supervision.

## RECOMMENDED USE

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

## HOW SUPPLIED

Commercial Product (90 Caplets)  
00525-0555-90

Rx

Professional Sample (6 Caplets)  
00525-0555-06

Not for Sale

Available as an oval coated beige colored caplet. Debossed with "LMF" on one side and "6RF" on the other.

## STORAGE

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

Metafolin® is a trademark of Merck KGaA, Germany

Manufactured and Distributed by  
Alfasigma USA, Inc.  
Shreveport, LA 71103

## Questions?

Call 1-844-639-9726

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