

## DEPLIN® 7.5 Capsules

## DEPLIN® 15 Capsules

### DESCRIPTION

DEPLIN® is a prescription medical food for use only under the supervision of a physician for the clinical dietary management of depression and schizophrenia and is specially formulated to meet the distinctive nutritional requirement for these conditions.

Each DEPLIN® 7.5 capsule contains 7.5 mg of L-methylfolate (from Metafolin®)\* and 90.314 mg Algae-S powder (Schizochytrium). \*CAS#151533-22-1

Each DEPLIN® 15 capsule contains 15.0 mg of L-methylfolate (from Metafolin®)\* and 90.314 mg Algae-S powder (Schizochytrium). \*CAS#151533-22-1

### INGREDIENTS

#### DEPLIN® 7.5

Silicified Microcrystalline Cellulose, 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]), Pullulan, L-methylfolate Calcium, Titanium dioxide [color], Magnesium Stearate (Vegetable Source), FD&C Yellow #6 [color], FD&C Red #40 [color], Propylene Glycol, Sodium Hydroxide, Povidone, FD&C Yellow #6 Aluminum Lake, Shellac.

**Contains Milk and Soy**

#### DEPLIN® 15

Silicified Microcrystalline Cellulose, 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]), Pullulan, L-methylfolate Calcium, Titanium Dioxide [color], Magnesium Stearate (Vegetable Source), FD&C Yellow #6 [color], FD&C Red #40 [color], Propylene Glycol, Sodium Hydroxide, Povidone, Shellac. **Contains Milk and Soy**

**DEPLIN® is a prescription medical food for use only under the supervision of a physician.**

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.<sup>1</sup> **This product is not an Orange Book product.**

### INDICATIONS AND USAGE

#### CLINICAL DIETARY MANAGEMENT OF MAJOR DEPRESSIVE DISORDER

DEPLIN® is formulated to meet the distinctive nutritional requirement of individuals who have suboptimal L-methylfolate levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD). Please consult your physician for the use of DEPLIN® concomitant to antidepressant drugs.<sup>2-5</sup>

#### CLINICAL DIETARY MANAGEMENT OF SCHIZOPHRENIA

DEPLIN® is formulated to meet the distinctive nutritional requirement of individuals who have suboptimal L-methylfolate levels in the cerebrospinal fluid, plasma, and/or red blood cells and have schizophrenia who present with negative symptoms and/or cognitive impairment. Please consult your physician for the use of DEPLIN® concomitant to antipsychotics drugs.<sup>2</sup>

### CONTRAINDICATIONS

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

### PRECAUTIONS

#### GENERAL

L-methylfolate (DEPLIN®) is not interchangeable with folic acid. Folic acid is not effective in some patients in impacting cerebral folate levels due to low rates of folic acid transport across the blood-brain barrier and/or low

brain levels of the enzyme required to convert folic acid into a biological and functional form.<sup>7-9</sup>

Patients at risk for vitamin B12 deficiency should consult with their physician prior to taking L-methylfolate.<sup>10</sup>

### **PATIENT INFORMATION**

DEPLIN® is a prescription medical food for use only under the supervision of a physician.

### **ADVERSE REACTIONS**

Allergic reactions have been reported following the use of oral L-methylfolate.<sup>11</sup>

### **RECOMMENDED USE**

Adults: The usual adult dose is one DEPLIN® 15 capsule or one or two DEPLIN® 7.5 capsule(s), or given daily with or without food or as directed under medical supervision.

### **HOW SUPPLIED**

DEPLIN® is a prescription medical food for use only under the supervision of a physician.

DEPLIN® 7.5 Bottle of 90 Product Code # 00525-1139-90\*. Use under medical supervision.

Each DEPLIN® 7.5 capsule has an opaque orange cap and opaque white body. It is imprinted with “Deplin” in white ink on the cap and the “7.5” in orange ink on the body.

DEPLIN® 15 Bottle of 90 Product Code # 00525-1102-90\*. Use under medical supervision.

Blister of 6 Product Code #00525-1102-06\* Professional samples. Not for sale.

Each DEPLIN® 15 capsule has an opaque orange cap and opaque orange body. It is imprinted with “Deplin” in white ink on the cap and the “15” in white ink on the body.

\*Alfasigma USA, Inc. 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

U.S. Patent No. 7,674,490

### **REFERENCES**

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Questions?

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