

Supplement Facts

DESCRIPTION

Denovo[®] is a dietary supplement used for the metabolic management of low L-methylfolate (5-MTHF) levels associated with mood disorders.

INGREDIENTS

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 30
Each Capsule Contains the following:
Folate [as 15,000 mcg (15 mg) DFE (dietary folate equivalents) L-5-MTHF (From L-5-methyltetrahydrofolate calcium salt)]

Other ingredients: Microcrystalline cellulose, capsule (gelatin, titanium dioxide, FD&C yellow #5, FD&C yellow #6), vegetable magnesium stearate and silica.

CLINICAL PHARMACOLOGY

Denovo[®] contains L-methylfolate calcium salt which consists of a proprietary biologically active folate. It works to assist the body with regulating the synthesis or production of neurotransmitters found in the brain, such as serotonin, norepinephrine, and dopamine. Low levels of these neurotransmitters, which may be due to a genetic abnormality that reduces the body's ability to convert folate into the active compound, 5-MTHF, have been associated with depression. It is estimated that this genetic abnormality is found in approximately 70 percent of people suffering from depression. The most common of which is called Methylene tetrahydrofolate Reductase (MTHFR) genetic polymorphism, which compromises a person's ability to convert folic acid and dietary folate into 5-MTHF.

INDICATIONS AND USE

ADJUNCTIVE USE IN MOOD DISORDERS

Denovo[®] is indicated for the distinct nutritional requirements of individuals who have suboptimal levels of L-methylfolate 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} **Denovo**[®] is indicated regardless of MTHFR C677T polymorphism genotype.⁸

CONTRAINDICATIONS: **Denovo**[®] is contraindicated in patients with known hypersensitivity to any of the components contained in this product.

PRECAUTIONS

Folic acid, when administered in daily doses above 0.1 mg, 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). 5-MTHF may be less likely than folic acid to mask vitamin B12 deficiency.^{6,7} Folate therapy alone is inadequate for the treatment of a B12 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 mixed/manic episode in patients at risk for bipolar disorder. **Denovo**[®] is not an antidepressant. However, 5-MTHF has been shown to enhance antidepressant effects of known antidepressants.³ 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.

Denovo[®] should always be used under medical supervision.

PATIENT INFORMATION: **Denovo**[®] is a Dietary Supplement.

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 **Denovo**[®].

ADVERSE REACTIONS

Allergic reactions have not been reported following the use of oral (6S)-5-methyltetrahydrofolic acid, glucosamine salt.

DOSAGE AND ADMINISTRATION

Take one capsule daily as directed by a health care professional.

STORAGE Store at 15° - 30°C (59° - 86°F)

HOW SUPPLIED: **Denovo**[®] yellow opaque capsules are supplied in a bottle of 30 count, NDC 58407-1500-30, and a sample size package of 4 capsules per box, 58407-1500-04.

WARNING: Protect from heat, light, and moisture. Keep out of reach of children. Do not purchase if seal is broken.

REFERENCES: 1. Sequenced Treatment Alternatives to Relieve Depression (Star*D) Study, Am journal of Psy, January 2006. 2. Kelly CB, McDonnell AP, Johnston TG et. Al. J Psychopharmacol, 2004; 18(4):567-571. 3. Gilbody, S., Lewis, S., & Lightfoot T. Am J Epidemiol 2007; 165(1): 1-13 4. Stahl, S. M. CNS Spectrums 2007; 12(10):739-744. 5. Zajecka JM, Fava M, Shelton RC, Barrentine LW, Young P, Papakostas GI. Clin Psychiatry. 2016 May; 77(5):654-6010. 6. Akoglu B, et al. Euro J Clin Nutrition, 2007; 1-6. 7. Scott JM, Weir DG, The Lancet, 1981; 2(8242):337-40. [PMID:6115113]. 8. Willems FF, et al. Br J Pharmacol. 2004; 141(5):825-30. [PMID:14769778].

58407-1500-30

DENOVO[®]

15 mg (15,000 mcg DFE) of L-methylfolate calcium salt

Declare **VICTORY** with **DENOVO**[®]

Pick Numbers: ABC #10192197, Cardinal #5490362, McKesson #3567054, ANDA #328855, Smith Drug #869669, Morris Dickson #496554

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Many Patients who Feel Sad & Gloomy
Have an Unmet Dietary Need

Declare **VICTORY** with **DENOVO**[®]



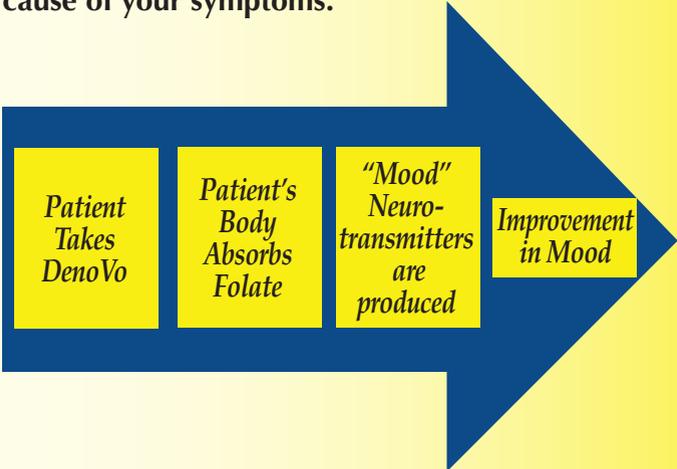
DENOVO[®]

An active folate dietary supplement,
without drug-related side effects

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DenoVo contains readily absorbable folate and is not folic acid, so the body does not require the MTHFR enzyme to absorb DenoVo. This is why the active folate in DenoVo may help people who cannot absorb the folic acid often included in store-bought vitamins. **DenoVo treats the root cause of your symptoms.**

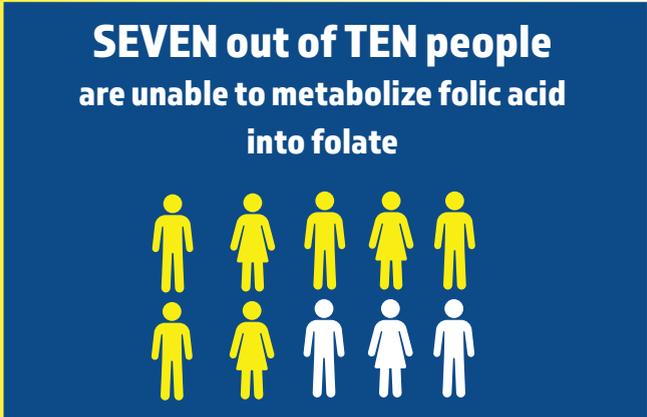


We need sufficient folate intake to help our bodies produce the essential neurotransmitters serotonin, dopamine, and norepinephrine. These neurotransmitters alleviate our feelings of sadness, anxiety, and gloom.

Age, weight, medications, nutrition, and genetics are among the factors that affect one's ability to absorb and produce sufficient folate.⁴ 70% of people in the United States lack a necessary enzyme (MTHFR) to metabolize folic acid into folate; folate is an essential vitamin for nerve and blood vessel repair and function.²

What symptoms can DenoVo® help?

- Sadness
- Anxiety
- Discouragement
- Hopelessness
- Short-temperedness
- Seasonal "blues"
- Gloominess
- Despair
- Irritability
- Stress
- Tearfulness
- Hypersensitivity



Each DenoVo capsule contains 15 mg (15,000 mcg DFE) of L-methylfolate calcium salt, which is the form of folate that is readily absorbed by our bodies. The recommended daily dosage is one capsule per day, which **may require up to 14 days for symptom improvement.**



DenoVo is not expensive (approximately \$1/day).

Declare *VICTORY* with *DENOVO*®

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Pharmacies can order DenoVo, or you may order directly from us online at www.magnaweb.com