

Hedonia™

August 27, 2024 - Update

A medical food for the clinical dietary management of depression and schizophrenia.

DESCRIPTION

Each capsule contains:

Dietary Ingredients:

470 mg of OMEGATEX8500 Omega-3 Triglycerides of which EPA is 400 mg, 46 mg are other Omega-3 Fatty Acids, and 24 mg DHA; and 300 mg of Aldonat Premium SAME Stabilized Powder; and 5.0 mg of L-Methylfolate Glucosamine as Quatrefolic

Other Ingredients:

Lemon Oil, Gellum gum, Titanium Dioxide, and Hypromellose

INDICATIONS AND USAGE CLINICAL DIETARY MANAGEMENT OF MAJOR DEPRESSIVE DISORDER

Hedonia™ is formulated to meet the distinctive nutritional requirement of individuals who have suboptimal L-methylfolate Calcium levels in the cerebrospinal fluid, plasma, and/or red blood cells and have major depressive disorder (MDD).
Omega-3 EPA
S-Adenosylmethionine (SAME)

Please consult your medical provider for the use of Hedonia™ concomitant to antidepressant drugs.

Hedonia™ is a medical food for use only under the supervision of a physician for the dietary management of major depressive disorder (MDD) and is specially formulated to provide the distinctive nutritional requirements of this condition. [1-7]

It is recommended that you check with your doctor before taking or adding Hedonia to your daily routine. If you are pregnant, nursing, diagnosed with bipolar disorder, and/or taking MAO Inhibitors, you should consult with your doctor first.

PRECAUTIONS

L-methylfolate **Glu Add** 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 bloodbrain barrier and/or low brain levels of the enzyme required to convert folic acid into a biological and functional form [8-10].

ADVERSE REACTIONS

Allergic reactions have been reported following the use of oral Quatrefolic, and Adonat.

CONTRAINDICATIONS

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

PATIENT INFORMATION

Hedonia™ is a medical food for use under medical supervision.

PATENT INFORMATION

Hedonia™ is Protected by U.S. Patent Nos. 8372451 & 9662359

RECOMMENDED USE

Usual adult dose is two Hedonia™ capsules twice a day with food or as directed under medical supervision.

HOW SUPPLIED

Commercial Product (120 capsules)
Available as a clear outer capsule, with a white inner capsule.

STORAGE

Store in a cool, dry place out of the reach of children. Store in a controlled room temperature of 15°C to 0°C (59°F to 86°F) Protect from heat, light, and moisture

Quatrefolic® is a registered trademark of Gnosis S.p.A., U.S. Patent No. 7,947,662.

Adonat® is a registered trademark of Gnosis S.p.A.

Manufactured by: VHNI® 172 E La Jolla St.
Placentia, CA 92870

Distributed by: HedoniaUSA Inc.
7475 Wisconsin Ave, Suite 1100, Bethesda, MD
20814

Questions?

Email: customerservice@hedoniausa.com

REFERENCES

1. Tobin, D.V., A.; Sarris, J., *Targeting Divergent Pathways in the Nutritional Management of Depression*. *Nutrients* 2024. **16**.
2. Godfrey, P.S., et al., *Enhancement of recovery from psychiatric illness by methylfolate*. *Lancet*, 1990. **336**(8712): p. 392-5.
3. Kelly, C.B., et al., *The MTHFR C677T polymorphism is associated with depressive episodes in patients from Northern Ireland*. *J Psychopharmacol*, 2004. **18**(4): p. 567-71.
4. Jiang, W., et al., *Long-Chain Omega-3 Fatty Acid Supplements in Depressed Heart Failure Patients: Results of the OCEAN Trial*. *JACC Heart Fail*, 2018. **6**(10): p. 833-843.
5. Keshavarz, S.A., et al., *Omega-3 supplementation effects on body weight and depression among dieter women with co-morbidity of depression and obesity compared with the placebo: A randomized clinical trial*. *Clin Nutr ESPEN*, 2018. **25**: p. 37-43.
6. Sarris, J., et al., *Adjunctive Nutraceuticals for Depression: A Systematic Review and Meta-Analyses*. *Focus (Am Psychiatr Publ)*, 2018. **16**(3): p. 328-340.
7. Delle Chiaie, R., P. Pancheri, and P. Scapicchio, *Efficacy and tolerability of oral and intramuscular S-adenosyl-L-methionine 1,4-butanedisulfonate (SAmE) in the treatment of major depression: comparison with imipramine in 2 multicenter studies*. *Am J Clin Nutr*, 2002. **76**(5): p. 1172s-6s.
8. Gilbody, S., S. Lewis, and T. Lightfoot, *Methylenetetrahydrofolate reductase (MTHFR) genetic polymorphisms and psychiatric disorders: a HuGE review*. *Am J Epidemiol*, 2007. **165**(1): p. 1-13.
9. Lewis, S.J., et al., *The thermolabile variant of MTHFR is associated with depression in the British Women's Heart and Health Study and a meta-analysis*. *Mol Psychiatry*, 2006. **11**(4): p. 352-60.
10. Papakostas, G.I., et al., *Effect of adjunctive L-methylfolate 15 mg among inadequate responders to SSRIs in depressed patients who were stratified by biomarker levels and genotype: results from a randomized clinical trial*. *J Clin Psychiatry*, 2014. **75**(8): p. 855-63.