

DENOVO- levomefolic acid capsule
Magna Pharmaceuticals, Inc.

Denovo

Supplement Facts

Serving Size: 1 capsule

Servings per Container: 30

Each capsule contains the following:

Folate [as 15,000mcg (as 15mg) 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

Warning and 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). 5-MTHF may be less likely than folic acid to mask vitamin B12 deficiency. 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 precipitation of 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. 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.

Safe Handling

Before using this product, tell your doctor or pharmacist of all of the products you use. Keep a list of all our 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.

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

Take One capsule daily as directed by a health care professional

Store at 15o-30°C (59°-86° F)

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

Indication and Use

Adjunctive use in mood disorders

Denovo is indicated for the distinct nutritional requirements for people who have suboptimal levels of

L-methylfolate in 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 antidepressant. Denovo is indicated regardless of MTHFR C6771 polymorphism genotype.

Principal Display Panel- Denovo

Denovo

Dietary Supplement

USUAL DOSAGE:
Take one capsule daily or as directed by a health care professional.

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

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

58407-1500-30

Supplement Facts
Serving Size: 1 Capsule

	Amount Per Capsule	% Daily Value
Folate (as L-5-methyltetrahydrofolate calcium salt)	15mg	3,750%

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

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.

MADE IN THE USA

30 Capsules | Dietary Supplement

DISTRIBUTED BY:
MAGNA
Pharmaceuticals, Inc.
Louisville, KY 40299
888-206-5525

www.magnaweb.com

LOT:
EXP:

DENOVO

levomefolic acid capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRC:58407-150
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	15 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
WATER (UNII: 059QF0K00R)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:58407-150-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		09/15/2020	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
shape	
size (solid drugs)	20 mm
scoring	1

Labeler - Magna Pharmaceuticals, Inc. (620988360)

Registrant - Magna Pharmaceuticals, Inc. (620988360)

Establishment			
Name	Address	ID/FEI	Business Operations
Magna Pharmaceuticals, Inc.		620988360	label(58407-150)

Revised: 9/2020

Magna Pharmaceuticals, Inc.