

NIVA-FOL- pyridoxine, folic acid, and cyanocobalamin tablet
Nivagen Pharmaceuticals, Inc.

Niva-Fol™ Tablets

Medical Food

Each Niva-Fol™ Tablet contains:

Vitamin B ₆ (as Pyridoxine HCl)	25 mg
Folacin (Folic Acid)	2.5 mg
Vitamin B ₁₂ (as Cyanocobalamin)	2 mg

Other Ingredients:

Carmines, Calcium Carbonate, Magnesium Stearate, Stearic Acid, Starch, Croscarmellose Sodium, Silicon Dioxide, and Shellac. Contains no sugar, salt, yeast, milk, egg, shellfish, preservatives, artificial flavors or color.

INDICATIONS AND USAGE

For the dietary management of individuals with distinct nutritional needs under a physician or health-care provider's supervision for hyperhomocysteinemia; with particular emphasis for individuals with or at risk for atherosclerotic vascular disease in the coronary¹, peripheral², or cerebral³ vessels, or vitamin B₁₂ deficiency⁴. Niva-Fol™ Tablets are labeled as a medical food intended for use under active and ongoing medical supervision requiring medical care on a recurring basis for, among other things, instructions on the use of the medical food.

MEDICAL FOODS

Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has 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 a normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

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.

PRECAUTIONS

Folacin (folic acid) when administered as a single agent in doses above 0.1 mg daily, may

obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The 2 mg of cyanocobalamin contained in Niva-Fol™ Tablets has been shown to provide an adequate amount of cyanocobalamin to address this precaution⁵. Unmetabolized folic acid has been shown in one study of 105 postmenopausal women (50-75 yrs) to have the potential to reduce natural killer cells' cytotoxicity, which may result in an impaired immune response⁶.

Cyanocobalamin should not be used in those with Leber's optic atrophy. Decreased levels of B₁₂ have been associated with reduced ability to detoxify the cyanide in exposed individuals and cyanocobalamin may increase the risk of irreversible neurological damage from optic atrophy in those affected with the disorder. Hydroxocobalamin can aid in the detoxification of cyanide. This form of B₁₂ is an acceptable form for B₁₂ supplementation in those with this disorder.

Pregnant women and nursing mothers should only use 12 microgram doses of B₁₂ (cyanocobalamin) from nutritional supplements. Doses higher than this should only be recommended by your physician. Administration of doses of vitamin B₁₂ greater than 10 micrograms daily may produce a hematological response in those with anemia secondary to folate deficiency.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folacin (folic acid). Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema, and the feeling of swelling of the entire body has been associated with cyanocobalamin.

CONTRAINDICATIONS

Known hypersensitivity to any of the components in the product is a contraindication.

DRUG INTERACTIONS

Pyridoxine supplements should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine. However, pyridoxine may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folacin (folic acid) may result in decreased phenytoin effectiveness.

PATIENT INFORMATION

Niva-Fol™ Tablets are for use only under the direction and supervision of a licensed physician or health-care provider.

DOSAGE AND ADMINISTRATION

Usual adult dosage is one to two tablets daily, or as directed by a physician or health-care provider.

HOW SUPPLIED

Niva-Fol™ Tablets are available as an oval, coated tablet, debossed "N080". Supplied in bottles of 90 Tablets, 75834-080-90

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F).

See USP Controlled Room Temperature.

Protect from light and moisture.

Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

WARNING: KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Medical Food

All substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

To report a serious adverse event contact: 1-877-977-0687

Manufactured for:

**Nivagen Pharmaceuticals, Inc.
Sacramento, CA 95827**

References

^{1, 2} Eikelboom JW, Lonn Eva, Genest Jr Jaques, Hankey Graeme, Yusuf Salim: Homocysteine and Cardiovascular Disease: A Critical Review of the Epidemiologic Evidence. *Ann Intern Med.* 1999; 131:363-375.

³ The Homocysteine Studies Collaboration: Homocysteine and Risk of Ischemic Heart Disease and Stroke. *JAMA* 2002; Vol 288, No. 16:2015-2022.

⁴ Refsum Helga, Smith A. David, Ueland Per M, Nexo Ebba, Clarke Robert, McPartlin Joseph, Johnston Carole, Engbaek Frode, Schneede Jorn, McPartlin Catherine, and Scott John M.: Facts and Recommendations about Total Homocysteine Determinations: An Expert Opinion. *Clinical Chemistry* 2004; 50(1):3-32.

⁵ Kuzminski AM, Del Giacco EJ, Allen RH, et al: Effective Treatment of Cobalamin Deficiency with Oral Cobalamin. *Blood* 1998; 92:1191-1198.

⁶ Troen AM, Mitchell B, Sorensen B, Wener MH, Johnston A, Wood B, Selhub J, McTiernan A, Yasui Y, Oral E, Potter JD, and Ulrich CM: Unmetabolized Folic Acid in Plasma is Associated with Reduced Natural Killer Cell Cytotoxicity among Postmenopausal Women.

PRINCIPAL DISPLAY PANEL - 90 Tablet Bottle Label

NIVAGEN

75834-080-90

Niva-Fol™
Tablets

Medical Food

90 Tablets

Do not use this product if the inner safety seal under the cap is torn, broken, or missing.

NIVAGEN
75834-080-90
Niva-Fol™
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Do not use this product if the inner safety seal under the cap is torn, broken, or missing.

Supplement Facts	
Serving Size: 1 Tablet	Servings Per Container: 90
Amount per Serving	% Daily Value
Vitamin B ₆ (as Pyridoxine HCl)	25 mg 1250%
Folicin (Vitamin B ₉)	2.5 mg 625%
Vitamin B ₁₂ (as Cyanocobalamin)	2 mg 33333%

Other Ingredients: Carmine, Calcium Carbonate, Magnesium Stearate, Stearic Acid, Starch, Croscarmellose Sodium, Silicon Dioxide, and Shellac. Contains no sugar, salt, yeast, milk, egg, shellfish, preservatives, artificial flavors or color.

DOSE AND ADMINISTRATION: Usual adult dosage is one to two tablets daily, or as directed by a physician or health-care provider. See packaged insert for complete product information.

WARNING: Keep this and all medications out of the reach of children. All substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

CAUTION: Folic Acid may obscure pernicious anemia in that the peripheral blood picture may revert to normal while neurological manifestations remain progressive. Allergic sensitization has been reported following both oral and parenteral administration of Folic Acid.

Storage: Store at controlled room temperature, 15°C to 30°C (59°F to 86°F) (See USP).

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.

Call your licensed medical practitioner about side effects. You may report side effects by calling 877-977-0687.

Manufactured for:
Nivagen Pharmaceuticals, Inc.
Sacramento, CA 95827 USA
1-877-977-0687

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NIVA-FOL

pyridoxine, folic acid, and cyanocobalamin tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:75834-080
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	25 mg

Folic Acid (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	Folic Acid	2.5 mg
Cyanocobalamin (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	Cyanocobalamin	2 mg

Inactive Ingredients

Ingredient Name	Strength
Calcium Carbonate (UNII: H0G9379FGK)	
Magnesium Stearate (UNII: 70097M6I30)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Shellac (UNII: 46N107B710)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:75834-080-90	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		09/10/2021	

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	60 mm	
imprint		

Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Vitamins Laboratory Corp		928327774	MANUFACTURE(758324-080)

Revised: 9/2021

Nivagen Pharmaceuticals, Inc.