Niva-Fol™ Tablets

Medical Food

Each Niva-Fol™ Tablet contains:

- Vitamin B₆ (as Pyridoxine HCl) 25 mg
- Folacin (Folic Acid) 2.5 mg
- Vitamin B₁₂ (as Cyanocobalamin) 2 mg

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.

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 coronary, peripheral, or cerebral vessels, or vitamin B₁₂ deficiency. 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 precaution\(^5\). 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 response\(^6\).

Cyanocobalamin should not be used in those with Leber's optic atrophy. Decreased levels of B\(_{12}\) 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 B\(_{12}\) is an acceptable form for B\(_{12}\) supplementation in those with this disorder.

Pregnant women and nursing mothers should only use 12 microgram doses of B\(_{12}\) (cyanocobalamin) from nutritional supplements. Doses higher than this should only be recommended by your physician. Administration of doses of vitamin B\(_{12}\) 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


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
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<th>Strength</th>
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<tr>
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### Inactive Ingredients

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### Packaging

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### Marketing Information

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### Supplement Facts

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<tr>
<th>Serving Size:</th>
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<td>Amount Per Serving</td>
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### Labeler

Nivagen Pharmaceuticals, Inc. (052032418)

### Establishment

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<th>Name</th>
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<tr>
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<td>928327774</td>
<td>MANUFACTURE(758324-080)</td>
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Revised: 9/2021