

NIVA-PLUS- folic acid, vitamin a, ascorbic acid, calcium sulfate, ferrous fumarate, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, zinc oxide, and cupric oxide tablet, coated Nivagen Pharmaceuticals, Inc.

**Niva-Plus™
Tablets**

Rx Only

DESCRIPTION

Niva-Plus™ is an orally administered prescription vitamin for the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation. Niva-Plus™ is an oval, beige tablet with "N050" debossed on one side.

Supplement Facts		
Servings per Bottle: 100		
Serving Size: 1 tablet	% DV Adults & Children 4 Years or More	
Each tablet contains:		
Folic Acid	1 mg	250 %
Vitamin A (Input as vitamin A acetate and beta carotene)	4000 IU	80 %
Vitamin C (ascorbic acid)	120 mg	200 %
Calcium (calcium sulfate)	200 mg	20 %
Iron (ferrous fumarate)	27 mg	150 %
Vitamin D₃ (cholecalciferol)	400 IU	100 %
Vitamin E (dl-alpha-tocopheryl acetate)	22 IU	157 %
Vitamin B₁ (thiamine mononitrate)	1.84 mg	123 %
Vitamin B₂ (riboflavin)	3 mg	176 %
Niacinamide (vitamin B ₃)	20 mg	100 %
Vitamin B₆ (pyridoxine HCl)	10 mg	500 %
Vitamin B₁₂ (cyanocobalamin)	12 mcg	200 %
Zinc (zinc oxide)	25 mg	167 %
Copper (cupric oxide)	2 mg	100 %

Other Ingredients: Microcrystalline Cellulose, Beige Color Coating (Hydroxypropylmethyl Cellulose, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, FD&C Yellow #6 Lake, FD&C Blue #2 Lake), Pregelatinized Starch, Croscarmellose Sodium, Di Calcium Phosphate, Magnesium Stearate, Stearic Acid, Fumed Silica, Ascorbyl Palmitate.

INDICATIONS AND USAGE

Niva-Plus™ is indicated for the supplemental requirements of patients with nutritional deficiencies or are in need of nutritional supplementation.

CONTRAINDICATIONS

This product is contraindicated in patients with known hypersensitivity to any of the ingredients.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

PRECAUTIONS

General

Folic acid, when prescribed as a single agent in doses above 0.1 mg daily, 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). Reduced folates may be less likely than folic acid to mask vitamin B₁₂ deficiency. Folate therapy alone is inadequate for the treatment of B₁₂ deficiency.

PATIENT INFORMATION

Niva-Plus™ is a prescription vitamin for the use only under the direction and supervision of a licensed physician.

INTERACTIONS

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

Drugs which may interact with folate include:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate. Additionally, concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the levels of this AED in the blood and allowing breakthrough seizures to occur.
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.
- Cholestyramine: Reduces folic acid absorption and reduces serum folate levels.
- Colestipol: Reduces folic acid absorption and reduces serum folate levels.
- Cycloserine: Reduces folic acid absorption and reduces serum folate levels.
- Dihydrofolate Reductase Inhibitors (DHFRIs): DHFRIs block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels. DHFRIs include aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim.
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of the 5-methyltetrahydrofolate active transport in the intestine.
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs have been shown to inhibit some folate dependent enzymes in laboratory experiments. NSAIDs include ibuprofen, naproxen, indomethacin and sulindac.
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.
- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts.
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine.
- Smoking and alcohol: Reduced serum folate levels have been noted.
- Sulfasalazine: Inhibits the absorption and metabolism of folic acid.

- Metformin treatment in patients with type 2 diabetes decreases serum folate.
- Warfarin can produce significant impairment in folate status after a 6 - month therapy.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid, as well as possibly the use of other forms of folates - including reduced folates. Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cyanocobalamin.

Ferrous Fumarate

Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and subside with continuation of therapy and physician encouragement. Although, the absorption of iron is best when taken between meals, occasional gastrointestinal disturbances may be controlled giving Niva-Plus™ shortly after meals.

DOSAGE AND ADMINISTRATION

Before, during and after pregnancy, one tablet daily, or as prescribed by a physician.

HOW SUPPLIED

Niva-Plus™ is supplied as:

Bottles of 100 tablets: 75834-050-01

KEEP OUT OF REACH OF CHILDREN

Rx Only

Manufactured for:

Nivagen Pharmaceuticals, Inc., Sacramento, CA 95827

nivagen.com

Rev. 09/14

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

75834-050-01

Rx Only

Niva-Plus™

Tablets

NIVAGEN

PHARMACEUTICALS

100 TABLETS

STORAGE

Store at room temperature 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [see USP controlled room temperature]. Dispense in a tight, light resistant container as defined by the USP with a child resistant closure. Protect from light and moisture and avoid excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

75834-050-01

Rx Only

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Call your doctor about side effects. You may report side effects by calling 1-877-977-0687.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. There are no implied or explicit claims on therapeutic equivalence.

KEEP OUT OF THE REACH OF CHILDREN.

Manufactured for:
Nivagen Pharmaceuticals, Inc.
Sacramento, CA 95827
nivagen.com

Rev. 09/14



Lot:
Exp:

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Peel label for prescribing and product information.

NIVA-PLUS

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Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRC:75834-050
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BO Y8) (FOLIC ACID - UNII:935E97BO Y8)	FOLIC ACID	1 mg
VITAMIN A (UNII: 8 1G40 H8 B0 T) (VITAMIN A - UNII:8 1G40 H8 B0 T)	VITAMIN A	4000 [iU]
ASCORBIC ACID (UNII: PQ6CK8 PD0 R) (ASCORBIC ACID - UNII:PQ6CK8 PD0 R)	ASCORBIC ACID	120 mg
CALCIUM SULFATE (UNII: WAT0 DDB50 5) (CALCIUM CATION - UNII:2M8 3C4R6 ZB)	CALCIUM SULFATE	200 mg
FERROUS FUMARATE (UNII: R5L488 RY0 Q) (FERROUS CATION - UNII:GW89 58 1O WR)	FERROUS CATION	27 mg
CHOLECALCIFEROL (UNII: 1C6 V77 QF4 1) (CHOLECALCIFEROL - UNII:1C6 V77 QF4 1)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO0 1)	.ALPHA.-TOCOPHEROL, DL-	22 [iU]
THIAMINE MONONITRATE (UNII: 8 K0 I0 49 19 X) (THIAMINE ION - UNII:4ABT0 J9 45 J)	THIAMINE	1.84 mg
RIBOFLAVIN (UNII: TLM29 76 O FR) (RIBOFLAVIN - UNII:TLM29 76 O FR)	RIBOFLAVIN	3 mg
NIACINAMIDE (UNII: 25 X5 1I8 RD4) (NIACINAMIDE - UNII:25 X5 1I8 RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68 Y4CF58 BV) (PYRIDOXINE - UNII:KV2JZ 1B I6 Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
CYANOCOBALAMIN (UNII: P6 YC3EG20 4) (CYANOCOBALAMIN - UNII:P6 YC3EG20 4)	CYANOCOBALAMIN	12 ug
ZINC OXIDE (UNII: SOI2LOH54 Z) (ZINC OXIDE - UNII:SOI2LOH54 Z)	ZINC OXIDE	25 mg
CUPRIC OXIDE (UNII: V1XJQ70 4R4) (CUPRIC CATION - UNII:8CBV6 7279 L)	CUPRIC CATION	2 mg

Inactive Ingredients

