

NUTRALYN- multivitamin tablet
Oncora Pharma, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Nutralyn is a prescription multivitamin/multimineral dietary supplement.

Nutralyn is a prescription multivitamin/multi-mineral dietary supplement formulated for the clinical dietary management of a suboptimal nutritional status in patients where advanced folate, vitamin B supplementation, and maintenance of good health is needed.

Nutralyn is contraindicated in patients with a known hypersensitivity to any of the ingredients.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B 12 deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNING Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In the case of accidental overdose, call a doctor or poison control center immediately.

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact Oncora Pharma at 888-321-2821.

One tablet daily or as directed by a physician.

Bottles of 30 Tablets (85477-903-30). Tablet is light blue, oblong.

*Oncora Pharma does not represent this product's code to be National Drug Code (NDC). Product codes are formatted according to standard industry practice, to meet the

formatting requirement by pedigree reporting and supply-chain control including pharmacies.

This product is a prescription-folate with or without other dietary ingredients - due to

increased folate levels increased risk associated with masking B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (64 FR 8760). 1-3 the most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription.

This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be Drug claims.

1.) Federal register Notice of August 2, 1973 (39 FR 20750)

2.) Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)

3.) Federal register notice of March 5, 1996 (61 FR 8760)

Storage and Handing

STORAGE: Store at 20- 25 degree C (68-77 F) excursions permitted to 15-30 degree C (59-86 F) {See USP controlled Room Temperature} Avoid excessive heat, light and moisture.

TAMPER EVIDENT: Do not use if seal is broken or missing.

MADE IN USA

Distributed by:

888-321-2821

Oncora Pharma

Dallas, TX 75161


KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

85477-903-30

Nutralyn™

DIETARY SUPPLEMENT


30 TABLETS




Dispensed by Prescription

DOSAGE AND ADMINISTRATION:
Usual adult dosage is 1 tablet taken orally once daily or as prescribed by a licensed medical practitioner.

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.


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STORAGE: Store at 20°-25°C (68°-77°F) excursions permitted to 15°-30°C(59°-86°F)[See USP Controlled Room Tempature] Avoid excessive heat, light and moisture.



Distributed by:
Oncora Pharma
Dallas, TX 75161
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SUPPLEMENT FACTS

Serving size Amount per serving:	1 tablet % Daily Value
Vitamin A (as Beta-Carotene)	300 mcg RAE 33%
Vitamin C (as Ascorbic Acid)	60 mg 67%
Vitamin D (as Cholecalciferol)	10 mcg 50%
Vitamin E (as d-Alpha Tocopherol Acetate)	4.5 mg (10 IU) 33%
Vitamin B6 (as Pyridoxine HCl)	26 mg 1529%
Biotin	0.280 mg 933%
Folate (from Folic Acid)	1.67 mg DFE 418% 0.67 mg DFE **
(from 5 Methyl Tetrahydrofolate Calcium Salt)	1 mg DFE **
Vitamin B12 (as Cyanocobalamin)	0.013 mg 542%
Calcium (as Calcium Carbonate)	60 mg 6%
Magnesium (as Magnesium Oxide)	25 mg 6%
Ferrocet™	20 mg 111mg
Iodine (as Potassium Iodide)	0.150 mg 100%

Other Ingredients: Microcrystalline Cellulose, Maltodextrin, Croscarmellose Sodium, Silicon Dioxide, Stearic Acid, Magnesium Stearate, Film Coating (Hydroxypropyl Methylcellulose, Polyethylene Glycol, Titanium Dioxide, FD&C Blue # 1)

NUTRALYN

multivitamin tablet

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:85477-903

Route of Administration		ORAL		
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
FERROUS BISGLYCINATE (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)		FERROUS CATION	20 mg	
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)		POTASSIUM IODIDE	0.15 mg	
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)		PYRIDOXINE	26 mg	
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)		BETA CAROTENE	0.3 mg	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)		ASCORBIC ACID	60 mg	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)		CHOLECALCIFEROL	0.1 mg	
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)		BIOTIN	0.28 mg	
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)		FOLIC ACID	1.67 mg	
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)		CYANOCOBALAMIN	0.013 mg	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)		CALCIUM CATION	80 mg	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)		MAGNESIUM CATION	25 mg	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)		.ALPHA.-TOCOPHEROL, DL-	4.5 mg	
Inactive Ingredients				
Ingredient Name			Strength	
STEARIC ACID (UNII: 4ELV7Z65AP)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
Product Characteristics				
Color	blue	Score	no score	
Shape	OVAL	Size	12mm	
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-903-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/24/2025	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved drug other		02/24/2025	
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Labeler - Oncora Pharma, LLC (119482542)

Revised: 4/2025

Oncora Pharma, LLC