

**FOLIXIA- 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.*

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**Folixia**

Folixia is a prescription multivitamin/multimineral dietary supplement.

Folixia 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.

Folixia 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 (85477-902-30). 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 Handling

**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

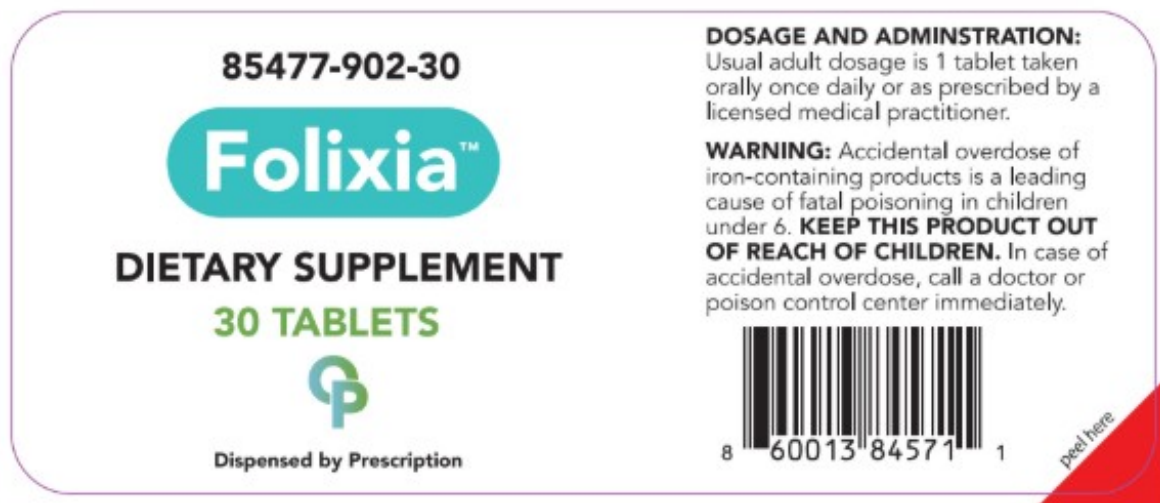
Distributed by:

888-321-2821

Oncora Pharma

Dallas, TX 75161

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN



## FOLIXIA

multivitamin tablet

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:85477-902
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FERROUS BISGLYCINATE</b> (UNII: SFW1D987QV) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	0.15 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	26 mg

<b>BETA CAROTENE</b> (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	0.3 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.1 mg
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	0.28 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.67 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	0.013 mg
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	80 mg
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	4.5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	

## Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85477-902-30	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	

**Labeler** - Oncora Pharma, LLC (119482542)