# FOLA-B COMPLEX- pyridoxine hydrochloride, folic acid, cyanocobalamin tablet Trifluent Pharma LLC

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## FOLA-B COMPLEX Dietary Supplement

FOLA-B COMPLEX - Rx only [Dispensed by Prescription]
Prescription only Folic Acid Containing Dietary Supplement

**FOLA-B COMPLEX** 

ACTIVE INGREDIENTS: Each tablet contains pyridoxine hydrochloride, folic acid, cyanocobalamin.

Serving Size: 1 Tablet
Serving per Container: 30

Each Tablet Contains:

Vitamin B-6 (as Pyridoxine HCl)

Folate

Vitamin B-12
(as Cyanocobalamin)

Serving Size: 1 Tablet

90

Marca Serving per Container: 30

10

Marca Serving per Container: 30

10

Marca Serving per Container: 30

10

Marca Serving per Container: 30

Marca Serv

**OTHER INGREDIENTS:** Calcium Phosphate, Modified Cellulose, Stearic Acid, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Triacetin, Polydextrose, Wax.

### DESCRIPTION

FOLA-B COMPLEX is an orally administered prescription only dietary supplement.

### INDICATIONS

FOLA-B COMPLEX<sup>TM</sup> tablets are indicated for nutritional support and folic acid supplementation.\*

## CONTRADINDICATIONS

FOLA-B COMPLEX is contraindicated in patients with a known hypersensitivity to any of the ingredients.

#### WARNING

Keep this and all medications out of the reach of children.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other

megaloblastic anemias where Vitamin B12 is deficient.

## **ADVERSE REACTIONS**

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: Trifluent Pharma, LLC at 1-210-944-6920.

## DOSAGE AND ADMINISTRATION

One tablet daily with food or as directed by a physician.

Before, during and/or after pregnancy, one tablet daily with food or as directed by a physician.

## PRECAUTION:

Folic acid in doses as low as 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive.

## **STORAGE**

Store at 20°-25°C (68°-77°F) excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Avoid excessive heat, light and moisture.

## **How Supplied**

Fola-B Complex, 30 Tablets in a bottle, 73352-890-30^

Tablet is pink, round.

## Distributed by:

Trifluent Pharma, LLC, San Antonio TX

Rev 01 890-30

**TAMPER EVIDENT** Double safety sealed for your protection. Do not use if either seal is broken or missing.

### MADE IN USA

\*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

^Trifluent Pharma does not represent this product 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 that – due to increased folate levels increased risk associated with masking B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner. 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 statues 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 (38 FR 20750) 2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044) 3. Federal Register Notice of April 9, 1971 (36 FR 6843)

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Peel back label at the bottom corner for full prescribing information.



Distributed by: Trifluent Pharma, LLC San Antonio, TX 78213



## **FOLA-B COMPLEX**

pyridoxine hydrochloride, folic acid, cyanocobalamin tablet

## **Product Information**

Product Type DIETARY SUPPLEMENT Item Code (Source) NHRIC:73352-890

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

Ingradient Name Basis of Strongth

ingredient Name	Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ1BI6Z)	PYRIDOXINE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	400 ug

Inactive Ingredients		
Ingredient Name	Strength	
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
TRIACETIN (UNII: XHX3C3X673)		
POLYDEXTROSE (UNII: VH2XOU12IE)		
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NHRIC:73352-890-30	30 in 1 BOTTLE			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
dietary supplement		07/18/2025		

Supplement Facts			
Serving Size :		Serving per Container :	
	<b>Amount Per Serving</b>	% Daily Value	
color			
shape			
scoring	1		
size (solid drugs)	19 mm		

## Labeler - Trifluent Pharma LLC (117167281)

Revised: 7/2025 Trifluent Pharma LLC