

**FOLVITA COMPLEX- pyridoxine hydrochloride, folic acid,
cyanocobalamin tablet**
Aletris Pharmaceuticals, LLC

**FOLVITA
COMPLEX™
Dietary Supplement**

FOLVITA COMPLEX™ - Rx only [Dispensed by Prescription]
Prescription only Folic Acid Containing Dietary Supplement

FOLVITA COMPLEX™

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

Serving Size: 1 Tablet
Serving per Container: 30
Each Tablet Contains:

		% Daily Value
Vitamin B-6 (as Pyridoxine HCl)	10 mg	588%
Folate	1,667 mcg DFE (from 1,000 mcg Folic Acid)	417%
Vitamin B-12 (as Cyanocobalamin)	400 mcg	16,667%

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

DESCRIPTION

FOLVITA COMPLEX™ is an orally administered prescription only dietary supplement.

INDICATIONS

FOLVITA COMPLEX™ tablets are indicated for nutritional support and folic acid
supplementation.

CONTRADINDICATIONS

FOLVITA 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: Aletris Pharmaceuticals, LLC at 228-207-8112.

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.

Distributed by:

Aletris Pharmaceuticals, LLC,
Biloxi, MS 39532
(228) 207-8112

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60010-890-77*

FOLVITA COMPLEX™

Dietary Supplement

Rx only

30 TABLETS

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



Distributed by:
Alettris Pharmaceuticals, LLC
Biloxi, MS 39532
(228) 207-8112

FPO
UPC Barcode

Lot & Exp
Print Area
No
Varnish

½" x 1"
Minimum

Peel Here

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HOW SUPPLIED

Bottles of 30 tablets (60010-890-77*).
Tablet is pink, round.

60010-890-77*



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 statutes as applicable. The ingredients, indication, or claims of this product.

FOLVITA COMPLEX™ - Rx only (Dispensed by Prescription)
Prescription only Folic Acid Containing Dietary Supplement

FOLVITA COMPLEX™

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

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)

*Alettris Pharmaceuticals 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.

STORAGE AND HANDLING

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.

TAMPER EVIDENT

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

MADE IN USA

Distributed by:

Alettris Pharmaceuticals, LLC,
Biloxi, MS 39532
(228) 207-8112

*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.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.



60010-890-77*

Rev. 0

Supplemental Facts

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Serving per Container: 30

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FOLVITA COMPLEX

pyridoxine hydrochloride, folic acid, cyanocobalamin tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	86001089077
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1667 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	400 ug

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELOSE 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)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	86001089077	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/07/2025	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	

shape	
scoring	1
size (solid drugs)	19 mm

Labeler - Aletris Pharmaceuticals, LLC (118956541)

Establishment			
Name	Address	ID/FEI	Business Operations
Aletris Pharmaceuticals, LLC		118956541	