

FOLVITRA- folic acid, vitamin d3 tablet
Blue Heron Pharmaceuticals, 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.

Folvitra

HEALTH CLAIM:

Folvitra - Vitamin D3 and Folic Acid Tablets

SUPPLEMENT FACTS		
Serving Size: 1 tablet		
Servings Per Container: 30		
Amt. Per Serving:	%DV ‡	
Vitamin D3 (as Cholecalciferol)	125 mcg (5000 IU)	625%
Folic Acid	1000 mcg	417%
**% Daily value not established		

Inactive Ingredients: Modified Vegetable Cellulose, Dicalcium Phosphate Dihydrate, Croscarmellose Sodium, Stearic Acid, Silicon Dioxide (39% Si), Magnesium Stearate.

DESCRIPTION:

Folvitra Multivitamin Capsules are clear capsules dispensed in plastic bottles of 30 ct.
85622-0004-30

Reserved for Professional Recommendation

Folvitra is an orally administered prescription folate product for the dietary management of patients with unique nutritional needs requiring increased folate levels and Vitamin D supplementation due to Vitamin D deficiency.

Folvitra Tablets should be administered under the supervision of a licensed medical practitioner.

This listed product is not a National Drug Code, but instead has merely been formatted to comply with standard industry practice for pharmacy and insurance computer

systems.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:

Blue Heron Pharmaceuticals

Lutz, FL 33559

WARNINGS:

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

Folvitra Tablets should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

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Tell your doctor if you have: kidney problems, thyroid disease. This medication should be used as directed during pregnancy or while breast-feeding. Consult your doctor about the risks and benefits.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

DOSAGE:

Usual adult dose is 1 tablet by mouth daily once daily, or as prescribed by a licensed medical practitioner.

PRECAUTIONS:

CONTRAINDICATIONS

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ADVERSE REACTIONS

Allergic sensitizations have been reported following oral administration of folic acid.

Consult your physician immediately if adverse side effects occur.

KEEP OUT OF THE REACH OF CHILDREN.

STORAGE:

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.] Protect from light and moisture.

Label:

Dosage: Usual adult dose is one tablet daily, or as prescribed by a licensed medical practitioner.

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KEEP OUT OF THE REACH OF CHILDREN.

STORAGE: Store at 20° to 25°C (68° to 77°F); excursions permitted to 1 5° t o 3 0°C (59° t o 8 6°F). [See USP Controlled Room Temperature.] Protect from light and moisture.

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Lot:
EXP:


85622-0004-30


Folvitra
TABLETS
Dispensed by Prescription
30 TABLETS
DIETARY SUPPLEMENT

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Manufactured for:
Blue Heron Pharmaceuticals
2831 Allegra Way Suite 218 Lutz FL 33559
Questions? Call: 813-380-0271
www.blueheronpharma.com

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FOLVITRA
folic acid, vitamin d3 tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:85622-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	125 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Product Characteristics			
Color	yellow	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85622-004-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	10/13/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/11/2025	

Labeler - Blue Heron Pharmaceuticals, LLC (137019051)

Establishment			
Name	Address	ID/FEI	Business Operations
Neeyan LLC		118819217	manufacture(85622-004)