

FOLTRATE- folic acid and cyanocobalamin tablet, film coated
Poly Pharmaceuticals, Inc.

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](#).

Drug Facts

Active Ingredients

(each tablet contains)

Folic Acid

Cyanocobalamin (Vitamin B-12)

Description

Foltrate is a dietary supplement intended for oral administration

Inactive ingredients:

dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, silica, magnesium stearate, hydroxypropyl methylcellulose, and polyethylene glycol.

Indications and Usage

Foltrate is indicated for folic acid supplementation and general nutritional support. May also be recommended for patients who are of advancing age or suffer from improper food intake.

Contraindications

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

Precautions

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. The 500 mcg of cyanocobalamin (B-12) contained in each tablet of Foltrate should address this precaution.

Adverse reactions

Allergic sensitization following oral and parenteral administration of folic acid has been reported.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Dosage and Administration

Adults-one tablet daily or as directed by a physician.

How Supplied

Foltrate tablets are round, pink and film-coated. Each tablet is imprinted with "PE" on one side and "122" on the other. Foltrate tablets are available in bottles of 100 Tablets (NDC# 50991-323-01).

WARNING: KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.

Dispense in a tight, light resistant container as defined in USP/NF with a child-resistant closure.

Other information

Store at controlled room temperature, 15°-30°C (59°-86°F). Protect from light and moisture.

Rx only

Manufactured for:
Poly Pharmaceuticals, Inc.
Quitman, MS 39355

Rev. 11/11

Principal Display Panel

NDC 50991-323-01

Foltrate

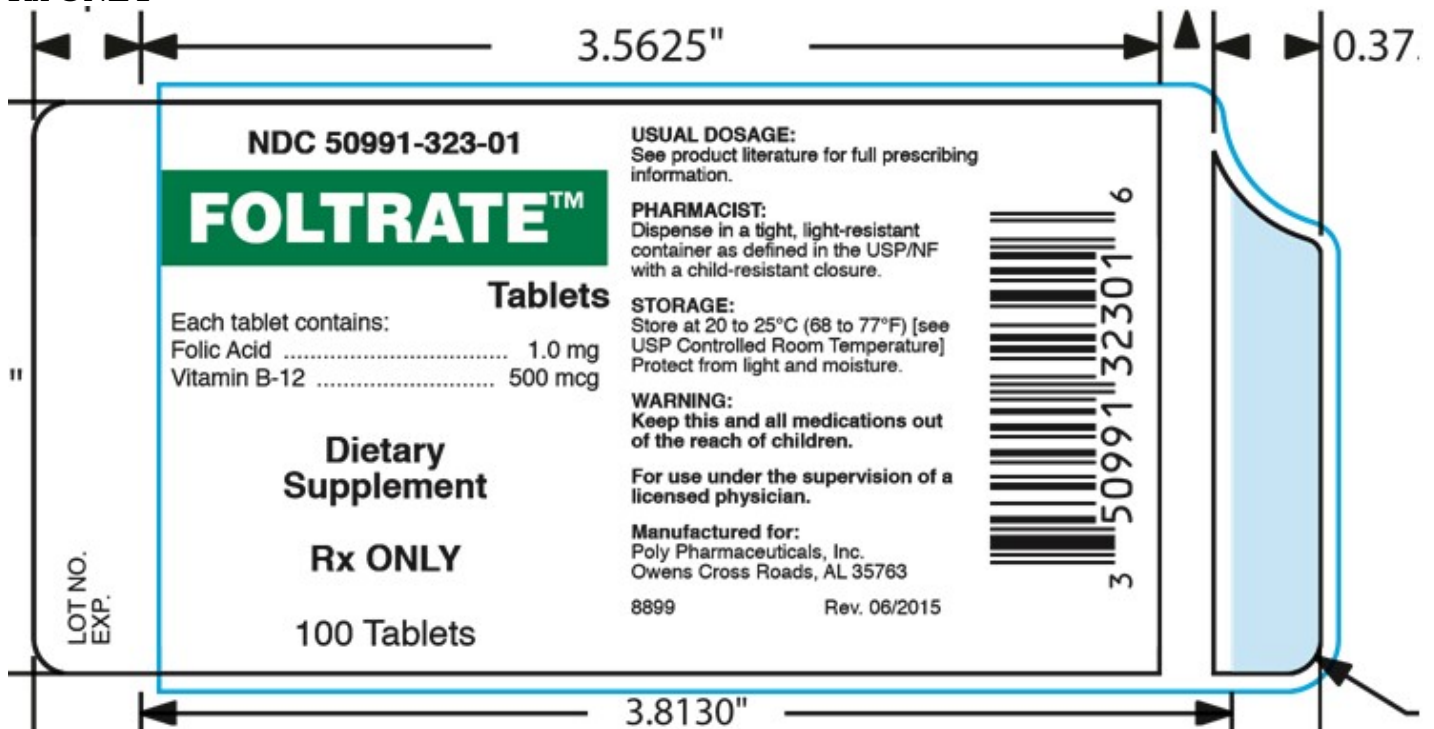
Tablets

Each tablet contains:

Folic Acid 1.0 mg

Vitamin B-12 500 mcg

Rx ONLY



FOLTRATE

folic acid and cyanocobalamin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50991-323
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANO COBALAMIN (UNII: P6 YC3EG204) (CYANOCOBALAMIN - UNII:P6 YC3EG204)	CYANOCOBALAMIN	500 ug

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	PE;122
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-323-25	12 in 1 CARTON	08/26/2010	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:50991-323-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/26/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/26/2010	

Labeler - Poly Pharmaceuticals, Inc. (198449894)

Establishment			
Name	Address	ID/FEI	Business Operations
Monarch PCM, LLC		080000294	manufacture(50991-323)

Revised: 4/2019

Poly Pharmaceuticals, Inc.