

**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.*

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**Foltrate**

**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**

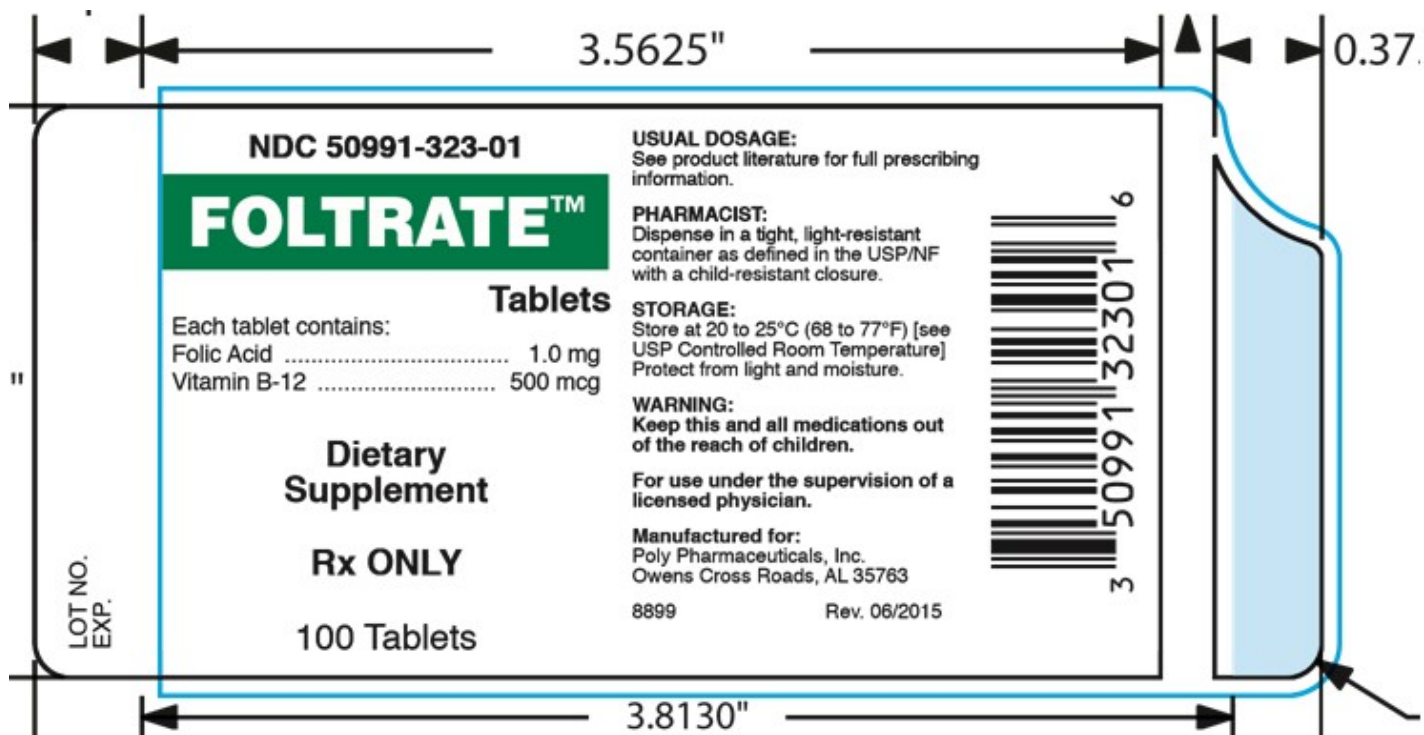
**Tablets**

**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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	500 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50991-323-25	12 in 1 CARTON	08/26/2010	01/27/2024
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)

Revised: 1/2024

Poly Pharmaceuticals, Inc.