

**FOLCYTEINE- multivitamin tablet**  
**PureTek Corporation**

*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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**Folcyteine**

**DESCRIPTION:**

Each caplet contains:

Vitamin D3 (as Cholecalciferol) ..... 20 mcg (800 IU)  
Folate (as Folic Acid)...1,667 mcg DFE (1,000 mcg Folic Acid)  
Calcium (as Calcium Citrate)..... 47 mg  
Magnesium (as Magnesium Citrate)..... 16 mg  
N-Acetyl-L-Cysteine..... 200 mg

**Other Ingredients:**

Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Sodium Carboxymethyl Starch, Stearic Acid, Coating: (Hydroxypropyl Methylcellulose, PEG-8).

**Indications and Usage:**

**Folcyteine**<sup>™</sup> is indicated to provide vitamin supplement to men and women. Folic acid is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid (as may be seen in tropical or nontropical sprue) and in anemias of nutritional origin, pregnancy, infancy, or childhood

**Contraindications:**

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. **Folcyteine**<sup>™</sup> is contraindicated in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D.

### **Warnings:**

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. Administration of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

### **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. There is a potential danger in administering folic acid to patients with undiagnosed anemia, since folic acid may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

### **For use on the order of a healthcare practitioner.**

Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873** or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### **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 PureTek Corporation, at 1-877-921-7873.

### **Dosage and Administration:**

One (1) **Folcyteine**<sup>™</sup> caplet daily or as directed by a physician. Do not administer to children under the age of 12.

### **How Supplied:**

**Folcyteine**<sup>™</sup> are pale yellow, clear coated caplets in bottles containing 30 caplets – NDC 59088-795-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

### **Storage**

**Do not use if bottle seal is broken.**

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

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

To report a serious adverse event or to obtain product information, contact **877-921-7873**.

**Manufactured by:**

**PureTek Corporation** Panorama City, CA 91402

For questions or information call toll-free: **877-921-7873**

**Folcyteine™**


**Manufactured in the USA by:**

**PureTek Corporation**

Panorama City, CA 91402

For questions or information call toll-free: **877-921-7873**

59088-795-54
Rx Only



**Folcyteine™**

**Multivitamin**

Use under direction of a medical practitioner

**Supplement Facts**

Serving Size: 1 Caplet  
Servings per container: 30

	Amount Per Serving	%DV
Vitamin D3 (as Cholecalciferol)	20 mcg (800 IU)	100%
Folate (as Folic Acid)	1,667mcg DFE (1,000 mcg Folic Acid)	417%
Calcium (as Calcium Citrate)	47 mg	4%
Magnesium (as Magnesium Citrate)	16 mg	4%
N-Acetyl-L-Cysteine	200 mg	*

\*Daily Value not established

**Dosage:** Usual Adult dose is one caplet once daily, or as prescribed by a licensed medical practitioner.

If you are pregnant or nursing, ask a healthcare professional.

Folcyteine™ should be administered under the supervision of a licensed medical practitioner.

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**PureTek Corporation**  
 Panorama City, CA 91402  
 Questions? Call toll-free:  
 1-877-921-7873

List No: 79554IAA Rev: 38745



N 3 59088 79554 5

**Other Ingredients:** Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Sodium Carboxymethyl Starch, Stearic Acid, Coating: (Hydroxypropyl Methylcellulose, PEG-8).  
**Store at 20° to 25°C (68° to 77°F). Keep in a cool dry place.**

FOLCYTEINE			
multivitamin tablet			
Product Information			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:59088-795
<b>Route of Administration</b>	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>CALCIUM CITRATE</b> (UNII: MLM29U2X85) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CITRATE	47 mg	
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	800 [IU]	
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug	
<b>ACETYLCYSTEINE</b> (UNII: WYQ7N0BPYC) (ACETYLCYSTEINE - UNII:WYQ7N0BPYC)	ACETYLCYSTEINE	200 mg	
<b>MAGNESIUM CITRATE</b> (UNII: RHO26O1T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	16 mg	

## Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	

## Product Characteristics

Color	yellow (Pale Yellow)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-795-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/14/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/14/2023	

**Labeler** - PureTek Corporation (785961046)

Revised: 9/2023

PureTek Corporation