

FOLTAMIN- folic acid, vitamin d3 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.

Foltamin™

(Folic Acid, Vitamin D3 Tablet)
Rx Only

DESCRIPTION

Foltamin™ 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.

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

Each tablet contains:

Folate (as folic acid).....1700 mcg DFE†

(1000 mcg folic acid)

Vitamin D3 (cholecalciferol).....125 mcg (5000 IU)

Each tablet contains the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, stearic acid, magnesium stearate.

† Dietary Folate Equivalent

INDICATIONS AND USAGE

Foltamin™ is indicated for dietary management of patients with unique nutritional needs requiring increased folate levels and Vitamin D supplementation.

Foltamin™ can be taken by women of childbearing age, pregnant women, and lactating and nonlactating mothers.

CLINICAL PHARMACOLOGY

The *in vivo* synthesis of the major biologically active metabolites of Vitamin D occurs in two steps. The first hydroxylation of ergocalciferol takes place in the liver (to 25-hydroxyvitamin D) and the second in the kidneys (to 1,25-dihydroxyvitamin D). Vitamin D metabolites promote the active absorption of calcium and phosphorus by the small

intestine, thus elevating serum calcium and phosphate levels sufficiently to permit bone mineralization. Vitamin D metabolites also mobilize calcium and phosphate from bone and probably increase the reabsorption of calcium and perhaps also of phosphate by the renal tubules.

There is a time lag of 10 to 24 hours between the administration of vitamin D and the initiation of its action in the body due to the necessity of synthesis of the active metabolites in the liver and kidneys. Parathyroid hormone is responsible for the regulation of this metabolism in the kidneys.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

KEEP OUT OF THE REACH OF CHILDREN.

Tell your doctor if you have: kidney problems, thyroid disease. This medication should be used as directed during pregnancy or while breastfeeding. Consult your doctor.

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.

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

Take one tablet daily or as directed by a healthcare practitioner.

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

HOW SUPPLIED

Foltamin™ Tablets are supplied as round, light yellow tablets with one side scored, the other side plain and dispensed in child-resistant bottles of 30 tablets (NDC 59088-200-54*).

* This product is a prescription-folate with or without other dietary ingredients that – due

FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	125 ug

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	yellow (Light Yellow)	Score	2 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-200-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/29/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/29/2021	

Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation