FOLIXATE- folate, 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.

Folixate™

(Folic Acid, Vitamin D3 Tablet)
Rx Only

DESCRIPTION

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

Folixate™ should be administered under the supervision of a licensed healthcare practitioner.

Each tablet contains:
Folate (as L-5-Methyltetrahydrofolate calcium salt).....1700 mcg DFE
(1000 mcg of L-5-methylfolate)
Vitamin D3 (as Cholecalciferol).....125 mcg (5000 IU)

Each tablet contains the following inactive ingredients: Lactose Monohydrate, Magnesium Stearate, Microcrystalline Cellulose, Sodium Starch Glycolate, Vegetable Stearic Acid.

INDICATIONS AND USAGE

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

Folixate™ 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. **Folixate**™ is contraindicated in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of Vitamin D, and hypervitaminosis D.

WARNINGS AND PRECAUTIONS

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. Folate alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. Folate 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 folate.

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 licensed healthcare practitioner.

HOW SUPPLIED

Folixate™ 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 59088-301-54).

* This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels (AUG 2, 1973 FR 20750), requires an Rx on the label because of increased risk associated with masking of B12 deficiency (pernicious anemia). Based on our assessment of the risk of obscuring pernicious anemia, this product requires licensed healthcare practitioner supervision, an Rx status, and a National Drug Code (NDC) or similarly-formatted product code, as required by pedigree reporting requirements and supply-chain control as well as in some cases, for insurance-reimbursement applications.

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.

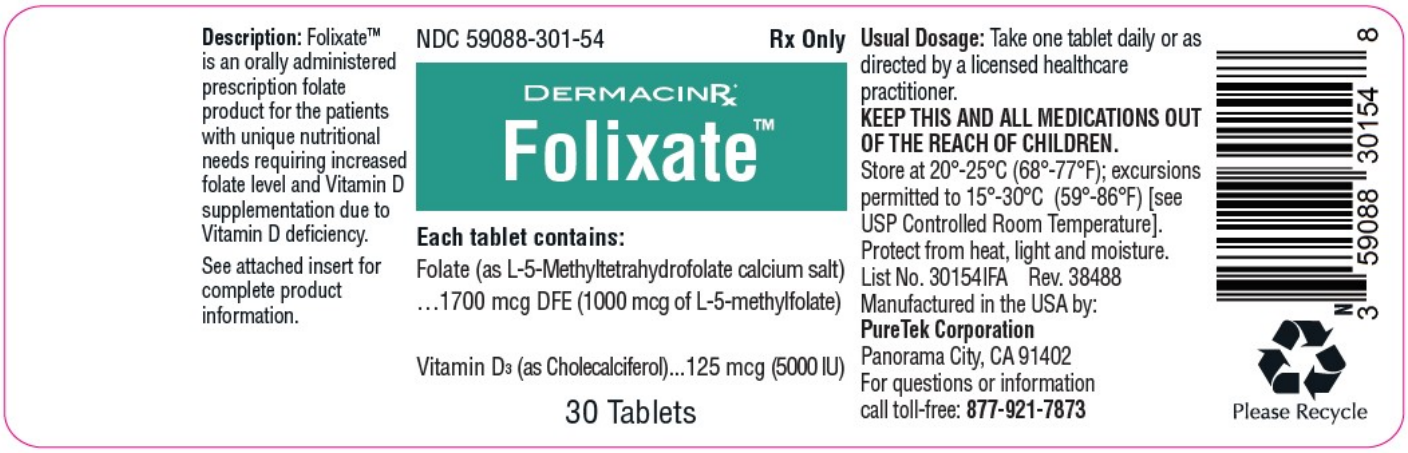
STORAGE

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

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

Tamper Evident: Do not use if seal is broken or missing.

Folixate™



FOLIXATE

folate, vitamin d3 tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-301
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1000 ug
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)	
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:59088-301-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/05/2023	

Labeler - PureTek Corporation (785961046)

Revised: 12/2023 PureTek Corporation