**FOLIXAPURE- 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.*

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**Folixapure Tablets**

**[Folate (as folic acid) 1700 mcg DFE (1000 mcg folic acid), VitaminD3 (cholecalciferol) 125 mcg (5000IU)]**

**Rx Only**

## DESCRIPTION

Folixapure™ 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.

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

Each tablet contains:

Folic Acid .....1700 mcg DFE

(1000 mcg folic acid)

Vitamin $D_3$ (cholecalciferol) .....125 mcg

5000 IU

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

## INDICATIONS AND DOSAGE

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

*Folixapure™ 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. Folixapure™ 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.

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.

## HOW SUPPLIED

Folixapure™ 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 59088-163-54*).

* 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 $B_{12}$ deficiency (pernicious anemia). Based on our assessment of the risk of obscuring pernicious anemia, this product requires

licensed medical 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 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

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: 877-921-7873

## PACKAGE LABEL / PRINCIPAL DISPLAY PANEL

Manufactured in the USA by:
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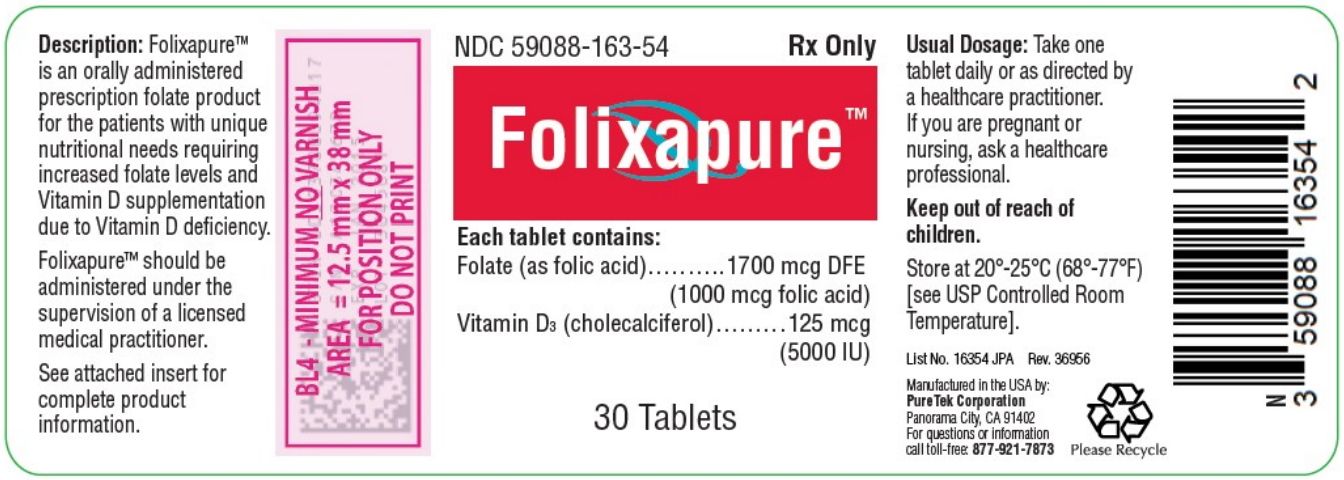
Panorama City, CA 91402
For questions or information
call toll-free: 877-921-7873

List No. 16354 JPA Rev. 36956



# FOLIXAPURE

folic acid, vitamin d3 tablet

## Product Information

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|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:59088-163 |
| **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 |
| **VITAMIN D** (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41) | VITAMIN D | 125 ug |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |
| **LACTOSE MONOHYDRATE** (UNII: EWQ57Q8I5X) | |
| **SODIUM STARCH GLYCOLATE TYPE A CORN** (UNII: AG9B65PV6B) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | 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:59088-163-54 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 07/10/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 07/10/2020 | |

## Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation