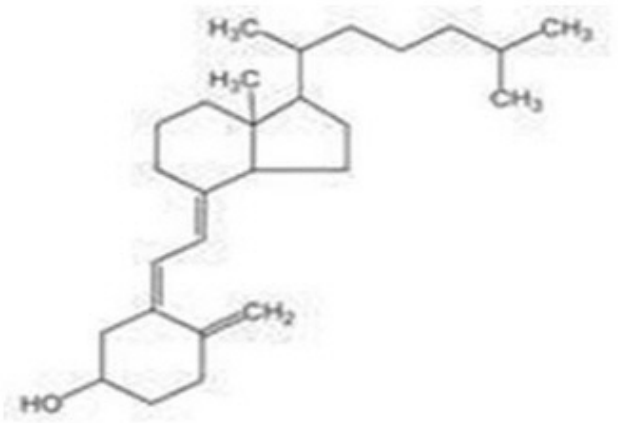
NOXIFOL-D- folic acid and cholecalciferol tablet, coated
SOLUTECH PHARMACEUTICALS LLC

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.

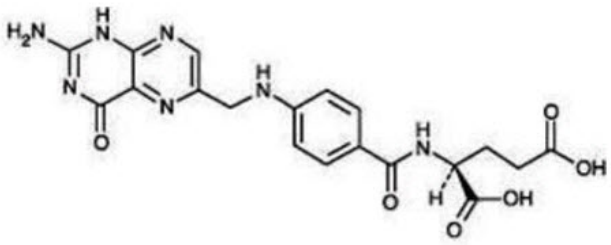
NOXIFOL-D

DESCRIPTION

Noxifol-D tablet is an orally administered prescription strength folate product for the dietary management of patients with unique nutritional needs requiring increased folate levels, Vitamin D levels, or used in improving the nutritional status of patients with folic acid and vitamin D deficiency. Noxifol-D should be administered under the supervision of a licensed medical practitioner. Vitamin D3 (cholecalciferol) is a white, crystalline powder, very soluble in water. Folic acid occurs as a yellow or yellowish-orange crystalline powder and is very soluble in water and insoluble in alcohol. The structural formula of Vitamin D3 and folic acid are as follows:



Vitamin D3 (cholecalciferol)



Folic Acid

Each tablet contains:

Folic Acid	1 mg
Vitamin D3 (Cholecalciferol)	2500 IU

Each tablet contains the following inactive ingredients: Microcrystalline Cellulose, Dicalcium Phosphate, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Pharmaceutical Glaze (Shellac), Carmine (color).

INDICATIONS AND USAGE

Noxifol-D is indicated for dietary management of patients with unique nutritional needs requiring increased folate levels, Vitamin D levels, or used in improving the nutritional status of patients with folic acid and vitamin D deficiency[1]

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1 This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent disease.

CLINICAL PHARMACOLOGY

The in vivo synthesis of the major biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation of Vitamin D 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.

Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Impairment of thymidylate synthesis in patients with folic acid deficiency is thought to account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic and macrocytic anemias.

Folic acid is absorbed rapidly from the small intestine, primarily from the proximal portion. Naturally occurring conjugated folates are reduced enzymatically to folic acid in the gastrointestinal tract prior to absorption. Folic acid appears in the plasma approximately 15 to 30 minutes after an oral dose; peak levels are generally reached within 1 hour.

CONTRAINDCATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients. Noxifol-D 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. In case of an accidental overdose, call a doctor or a poison control center immediately.

Tell your doctor if you have: kidney problems or thyroid disease.

This medication should be used as directed by your physician 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.

There is evidence that the anticonvulsant action of phenytoin is antagonized by folic acid. A patient whose epilepsy is completely controlled by phenytoin may require increased doses to prevent convulsions if folic acid is given.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

Call your doctor if you experience any of the following rare but possible signs of hypervitaminosis D: nausea, vomiting, constipation, loss of appetite, increased thirst, increased urination, mental/mood changes or unusual tiredness.

You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact Solutech Pharmaceuticals LLC, at 1-877-829-3135

DOSAGE AND ADMINISTRATION

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

HOW SUPPLIED

Noxifol-D tablets are dispensed in bottles of 30ct (NDC 70350-2602-3)

Noxifol-D tablets are pink, round, scored tablets with slightly scattered spots and debossed "ST" on one side and plain on the other side.

All prescriptions using this product shall be pursuant to state statutes as applicable. This product is an *Rx only* and 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.

Manufactured for:
Solutech Pharmaceuticals LLC
Peoria, AZ 85345

Rx only

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

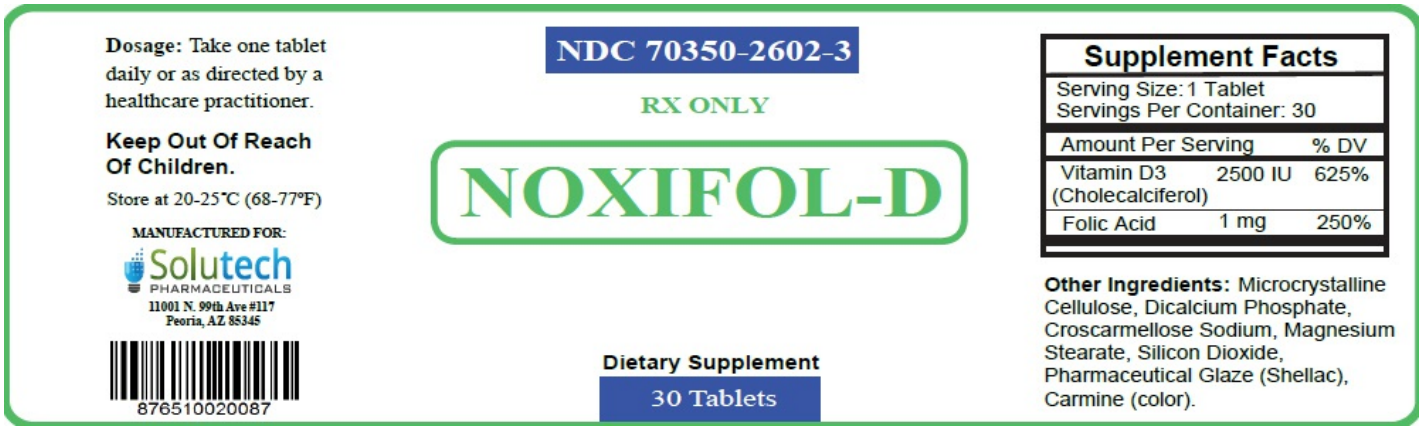
NDC 70350-2602-3

RX ONLY

NOXIFOL-D

Dietary Supplement

30 Tablets



NOXIFOL-D folic acid and cholecalciferol tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70350-2602
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
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	2500 [iU]

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SHELLAC (UNII: 46N107B71O)	
COCHINEAL (UNII: TZ8Z31B35M)	

Product Characteristics			
Color	PINK (SPOTTY)	**Score**	2 pieces
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	ST
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70350-2602-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/23/2018	

Labeler - SOLUTECH PHARMACEUTICALS LLC (080040396)

Revised: 4/2018 SOLUTECH PHARMACEUTICALS LLC