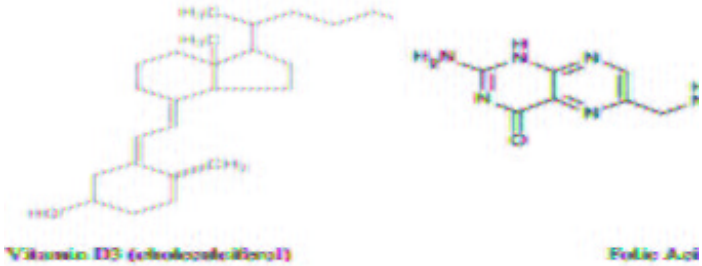
FOLVITE-D- folic acid and cholecalciferol tablet, coated
NEOMED PHARMACEUTICAL

FOLVITE-D

DESCRIPTION

FOLVITE-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. **FOLVITE-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 yellowishorange crystalline powder and is very soluble in water and insoluble in alcohol. The structural formula of Vitamin D3 and folic acid are as follows:



Each Tablet Contains:	
Folic Acid	1000 MCG
Vitamin D3 (Cholecalciferol)	94.375 MCG

Each tablet contains the following inactive ingredients: Microcrystalline Cellulose, Dicalcium Phosphate, Croscarmellose Sodium, Magnesium Stearate, Silicon Dioxide, Stearic acid, HPMC E15, HPMC E5/E6, PEG 8000.

INDICATIONS AND USAGE

FOLVITE-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.

DOSAGE:

Usual adult dose is 1 tablet once or twice daily or as prescribed by a licensed medical practitioner.

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. **FOLVITE-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 breastfeeding. 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.

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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 Neomed pharmaceutical, at 16315245758

HOW SUPPLIED

FOLVITE-D tablets are dispensed in bottles of 90ct (70898-409-09)
FOLVITE-D tablets are clear coated and caplet shaped tablets

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 (66°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from heat, light and moisture.

Manufactured for:

Neomed Pharmaceutical
Brentwood, NY 11717

FOLVITE-D

folic acid and cholecalciferol tablet, coated

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:70898-409
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	3775 [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)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:70898-409-09	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		06/07/2019	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	3 mm	

Labeler - NEOMED PHARMACEUTICAL (048388130)

Revised: 6/2019 NEOMED PHARMACEUTICAL