CHOLECAL DF- vitamin d, folic acid tablet
Amella Pharma LLC

CHOLECAL DF

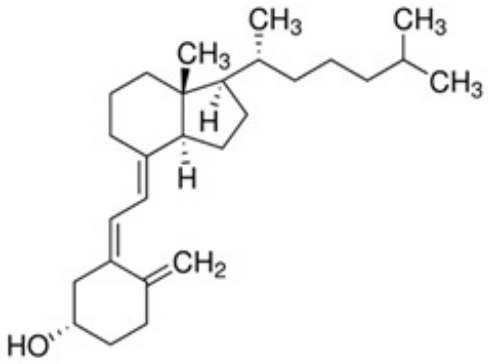
Rx Only
CHOLECAL DF Tablets Dietary Supplement
Dispensed by Prescription**

Supplement Facts	
Serving Size:1 Tablet	
Servings per container: 28	
Amount Per Serving:	**% Daily Value**
Vitamin D (as cholocalciferol) 95 mcg (3800 IU)	475%
Folate 1,666 mcg DFE (1 mg folic acid)	417%

STATEMENT OF IDENTITY
CHOLECAL DF Capsules 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 and other nutritional supplementation. CHOLECAL DF should be administered under the supervision of a licensed medical practitioner.

CHOLECAL DF capsules are supplied as a light yellow tablet with A1 imprinted on one side.

Vitamin D3 (cholecalciferol) is a white, crystalline powder, very soluble in water, with the following structural formula:



Each capsule contains:
Folic Acid..... 1,666 mcg DFE (1 mg)
Vitamin D3 (Cholecalciferol)..... 95 mcg (3800 IU)
Each capsule contains the following inactive ingredients: microcrystalline cellulose, stearic acid, pharmaceutical glaze, croscarmellose sodium, calcium stearate, and silicon dioxide.

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.

HEALTH CLAIM:

CHOLECAL DF is used for dietary management of patients with unique nutritional needs requiring increased folate levels, Vitamin D deficiency or are in need of Vitamin D supplementation and other nutritional supplementation.

CHOLECAL DF can be taken by women of childbearing age, pregnant women, and lactating and nonlactating mothers.

CONTRAINDICATIONS:

This product is contraindicated in patients with known hypersensitivity to any of the ingredients.

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 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. You may report adverse side effects to Amella Pharma, LLC, at 1-844-385-0850.

DOSAGE AND ADMINISTRATION:

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

KEEP OUT OF THE REACH OF CHILDREN.

HOW SUPPLIED:

CHOLECAL DF Tablets are supplied as a light yellow tablet with “A1” imprinted on one side.

CHOLECAL DF Tablets is dispensed in child-resistant bottles as the following:

72287-551-28* 28ct bottle

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.

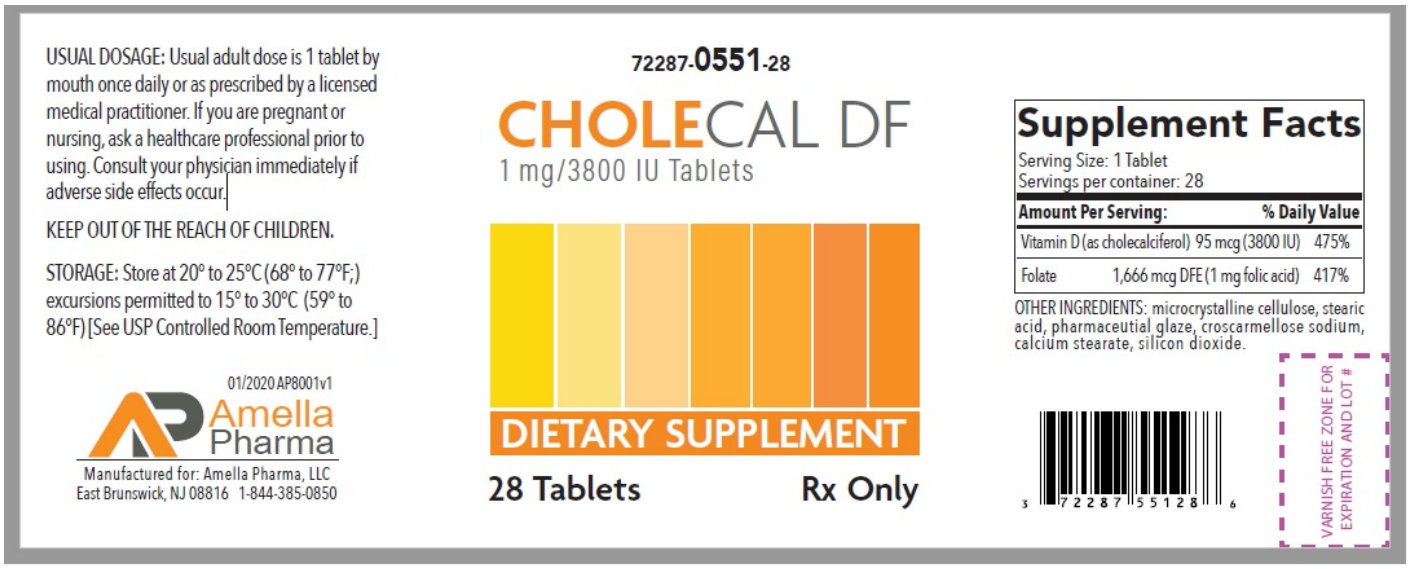
Tamper Evident: Do not use if seal is broken or missing.

Manufactured for:
Amella Pharma, LLC
E Brunswick, NJ 08816

Issued: 01/2020 AP8002v1

*Amella Pharma does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.
** 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 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.

Packaging



CHOLECAL DF

vitamin d, folic acid tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:72287-551
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	0.095 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Inactive Ingredients	
Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHELLAC (UNII: 46N107B71O)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72287-551-28	28 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		02/01/2020	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	11 mm	
scoring	1	
imprint		

Labeler - Amella Pharma LLC (081189492)

Revised: 2/2020 Amella Pharma LLC