

**CIFRAZOL- cifrazol capsule**  
**Sterling Knight 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.*

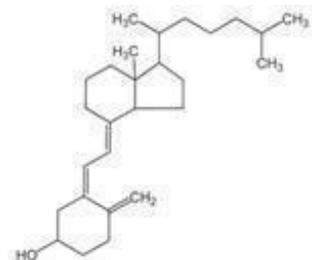
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**Cifrazol**

**DESCRIPTION**

Cifrazol is an orally administered prescription Vitamin for the dietary management of patients with unique nutritional needs requiring increased folate levels, Vitamin D supplementation due to Vitamin D deficiency and other nutritional supplementation.

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

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



Each capsule contains:

Folic Acid: 1mg, Vitamin D3 (Cholecalciferol): 3775IU

Each capsule contains the following inactive ingredients: Gelatin,Water, Soybean Oil, Yellow Wax, Lecithin,Glycerin, FD&C Red #40, FD&C Yellow #5, Titanium Dioxide.

**INDICATIONS AND USAGE**

Cifrazol is indicated 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.

**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. Cifrazol 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 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

## **ADVERSE REACTIONS**

This medication is generally well tolerated. Notify your doctor if you experience: nausea, loss of appetite, vomiting, stomach cramps, dry mouth, increased thirst, increased urination, muscle or bone pain, headache, weakness, weight loss, dizziness. If you notice other effects not listed above, contact your doctor or pharmacist.

## **DOSAGE AND ADMINISTRATION**

Take one capsule daily or as directed by a physician.

## **HOW SUPPLIED**

Cifrazol capsules are supplied as orange capsules printed with 300 dispensed in HDPE plastic bottles of 30ct.

**NDC 69336-310-30**

## **STORAGE AND HANDLING SECTION**

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place.

**Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

## **OTHER SAFETY INFORMATION**

Reserved for Professional Recommendation

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.

## **PACKAGE LABEL. PRINCIPAL DISPLAY PANEL**

**Rx Only**

**Reserved for Professional Recommendation**

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.

**DOSAGE:**

The usual adult dose is 1 capsule daily with or without food or as directed by a licensed medical practitioner.

**If you are pregnant or nursing a baby, ask a health professional**

**Caution:** This product contains soy. This product has been manufactured in a facility that also manufactures products containing tree nuts, peanuts, fish, egg, wheat, soy and shell fish. Individuals with allergic tendencies to these ingredients should use caution.

This product contains FD&C Yellow #5, soy and bovine gelatin.

**KEEP OUT OF REACH OF CHILDREN**

Call your Doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088. 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.

This product is Gluten Free



Rev. 10/15-1



Rx Only

NDC 69336-310-30



Store at 25° C (77° F); Excursions permitted to 15° - 30° C (59° - 86° F)  
[see USP Controlled Room Temperature]. Avoid exposure above 30° C (86° F).  
Protect from light and moisture.

30 Capsules

**DESCRIPTION**

Cifrazol is an orally administered prescription vitamin for the dietary management of patients with unique nutritional needs.

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

Cifrazol is available in a Orange capsule, imprinted in white ink "300"

**Each capsule contains:**

Folic Acid ..... 1 mg  
Vitamin D3 (cholecalciferol) ..... 3775 IU

Other Ingredients: Gelatin, Water, Soybean Oil, Yellow Wax, Lecithin, Glycerin, FD&C Red #40, FD&C Yellow #5, Titanium Dioxide.

See insert for more information



**Manufactured for:**  
Sterling Knight Pharmaceuticals, LLC  
Ripley, MS 38663

Lot #:  
Exp. Date

**Manufactured for:**

Sterling Knight Pharmaceuticals, LLC  
Ripley, MS 38663  
Rev. 1114-1

**CIFRAZOL**

cifrazol capsule

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:69336-310
<b>Route of Administration</b>	Oral		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	3775 [iU]
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

**Product Characteristics**

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	300
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69336-310-30	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/10/2017	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/10/2017	

**Labeler** - Sterling Knight Pharmaceuticals,LLC (079556942)

Revised: 1/2017

Sterling Knight Pharmaceuticals,LLC