DECALCITROL- cholecalciferol tablet, coated
Pharmin USA, LLC

DECALCITROL® CHOLECALCIFEROL (VITAMIN D3) 1.25 mg TABLETS (50,000 Units)

HIGH POTENCY SUPPLEMENT*

Warning:** Cholecalciferol 50000 IU can be classified as either a supplement or a medication in accordance with regulations set by health ministries in different countries. In USA, Cholecalciferol 50000 IU is a high potency supplement and **should be dispensed under direct clinical supervision.

DESCRIPTION

Decalcitrol (cholecalciferol-D3, Vitamin D3) is a fat-soluble high potency vitamin that helps your body absorb calcium and phosphorus.

Decalcitrol is a white, colorless crystal, insoluble in water, soluble in organic solvents, and slightly soluble in vegetable oils. It is affected by air and by light.

One Unit of vitamin D3 is equivalent to one International Unit (IU). Each Tablet, for oral administration, contains Cholecalciferol, 1.25 mg (equivalent to 50,000 USP units of Vitamin D).

Inactive Ingredients: Silica, magnesium stearate, cellulose, hydroxypropyl methylcellulose

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-dihydroxy- vitamin 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.

INDICATIONS AND USAGE

Colecalciferol Tablets are essential for absorption of calcium and necessary for healthy and strong bones. Cholecalciferol Tablets are indicated for use in the treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia.

CONTRAINDICATIONS

Colecalciferol Tablets are contraindicated in patients with hypercalcemia, malabsorption syndrome, abnormal sensitivity to the toxic effects of vitamin D, and hypervitaminosis D.

WARNINGS

Hypersensitivity to vitamin D may be one etiologic factor in infants with idiopathic hypercalcemia. In these cases vitamin D must be strictly restricted. Children under 12 years and pregnant women should consult a physician. Persons with kidney disease, bone disease, malignancies or calcium disorders should not take Vitamin D3 50000 IU except under the supervision of a physician.

Keep out of the reach of children.

PRECAUTIONS

General

Vitamin D administration from fortified foods, dietary supplements, self-administered and prescription drug sources should be evaluated. Therapeutic dosage should be readjusted as soon as there is clinical improvement. Dosage levels must be individualized and great care exercised to prevent serious toxic effects. When high therapeutic doses are used progress should be followed with frequent blood calcium determinations.

Maintenance of a normal serum phosphorous level by dietary phosphate restriction and/or administration of aluminum gels as intestinal phosphate binders in those patients with hyperphosphatemia as frequently seen in renal osteodystrophy is essential to prevent metastatic calcification.

Adequate dietary calcium is necessary for clinical response to vitamin D therapy.

Drug Interactions

Mineral oil interferes with the absorption of fat-soluble vitamins, including vitamin D preparations. Administration of thiazide diuretics to hypoparathyroid patients who are concurrently being treated with vitamin D preparations may cause hypercalcemia.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the drug's potential in these areas. A judgment of the physician is required.

Pregnancy Category C

For the protection of the fetus, the use of vitamin D in excess of the recommended dietary allowance during normal pregnancy should be avoided unless, in the judgment of the physician, potential benefits in a specific, unique case outweigh the significant hazards involved. The safety in excess of 400 units of vitamin D daily during pregnancy has not been established.

Nursing Mothers

Consult with physician is required.

Pediatric Use

Pediatric doses must be individualized.

Geriatric Use

Clinical studies of Colecalciferol did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. A few published reports have suggested that the absorption of orally administered vitamin D may be attenuated in elderly compared to younger individuals. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Geriatric requires seek their primary care physician before starting vitamin D therapy.

ADVERSE REACTIONS

Hypervitaminosis D is characterized by effects on the following organ system:

Renal: Impairment of renal function with polyuria, nocturia, polydipsia, hypercalciuria, reversible azotemia, hypertension, nephrocalcinosis, generalized vascular calcification, or irreversible renal insufficiency which may result in death.

CNS: Mental retardation.

Soft Tissues: Widespread calcification of the soft tissues, including the heart, blood vessels, renal tubules, and lungs.

Skeletal: Bone demineralization (osteoporosis) in adults occurs concomitantly.

Decline in the average rate of linear growth and increased mineralization of bones in infants and children (dwarfism), vague aches, stiffness, and weakness.

Gastrointestinal: Nausea, anorexia, constipation.

Metabolic: Mild acidosis, anemia, weight loss.

OVERDOSAGE

The effects of administered vitamin D can persist for two or more months after cessation of treatment.

Hypervitaminosis D is characterized by:

1. Hypercalcemia with anorexia, nausea, weakness, weight loss, vague aches and stiffness, constipation, mental retardation, anemia, and mild acidosis.
2. Impairment of renal function with polyuria, nocturia, polydipsia, hypercalciuria, reversible azotemia, hypertension, nephrocalcinosis, generalized vascular calcification, or irreversible renal insufficiency which may result in death.
3. Widespread calcification of the soft tissues, including the heart, blood vessels, renal tubules, and lungs. Bone demineralization (osteoporosis) in adults occurs concomitantly.
4. Decline in the average rate of linear growth and increased mineralization of bones in infants and children (dwarfism).

The treatment of hypervitaminosis D with hypercalcemia consists of immediate withdrawal of the vitamin, a low calcium diet, generous intake of fluids, along with symptomatic and supportive treatment. Hypercalcemic crisis with dehydration, stupor, coma, and azotemia requires more vigorous treatment. The first step should be hydration of the patient. Intravenous saline may quickly and significantly increase urinary calcium excretion. A loop diuretic (furosemide or ethacrynic acid) may be given with the saline infusion to further increase renal calcium excretion. Other reported therapeutic measures include dialysis or the administration of citrates, sulfates, phosphates, corticosteroids, EDTA (ethylenediaminetetraacetic acid), and mithramycin via appropriate regimens. With appropriate therapy, recovery is the usual outcome when no permanent damage has occurred. Deaths via renal or cardiovascular failure have been reported.

DOSAGE AND ADMINISTRATION

DOSAGE MUST BE INDIVIDUALIZED UNDER CLOSE MEDICAL SUPERVISION.

Calcium intake should be adequate. Blood calcium and phosphorus determinations must be made every 2 weeks or more frequently if necessary. X-rays of the bones should be taken every month until condition is corrected and stabilized

SWALLOW TABLETS. DO NOT CHEW. Take as directed by your physician.

Supplement Facts*	
Serving Size: One Tablet	
Each Tablet Contains:	Amount
Vitamin D3 (Cholecalciferol)	50,000 IU

HOW SUPPLIED

Bottles of 90 tablets (NDC 70586-1968-9).

Store at 20°– 25°C (68°–77°F) [See USP Controlled Room Temperature].

Protect from light and moisture.

Dispense in a tight, light-resistant container as defined in the USP.

Distributed by:

Pharmin USA, LLC

Mission Viejo, California 92691

United States of America

www.pharminusa.com

DECALCITROL is a registered trademark of Pharmin USA, LLC

Each tablet contains 50000 IU Vitamin D3

(Cholecalciferol) equivalent to 1.25 mg.

Vitamin D3 50,000 IU is essential for absorption of calcium and necessary for healthy bones and a healthy immune system.

Packaging

DECALCITROL

cholecalciferol tablet, coated

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:70586-1968
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	50000 [iU]

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NHRIC:70586-1968-9	90 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
dietary supplement		01/05/2011	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving	% Daily Value
color	
shape	
size (solid drugs) 13 mm	
scoring 1	

Labeler - Pharmin USA, LLC (025964216)

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
Pharmin USA, LLC		025964216	manufacture(70586-1968)

Revised: 12/2017 Pharmin USA, LLC