ERGOCALCIFEROL - ergocalciferol capsule
Dispensing Solutions, Inc.

Rx Only

DESCRIPTION

Ergocalciferol Capsules, USP is a synthetic calcium regulator for oral administration.

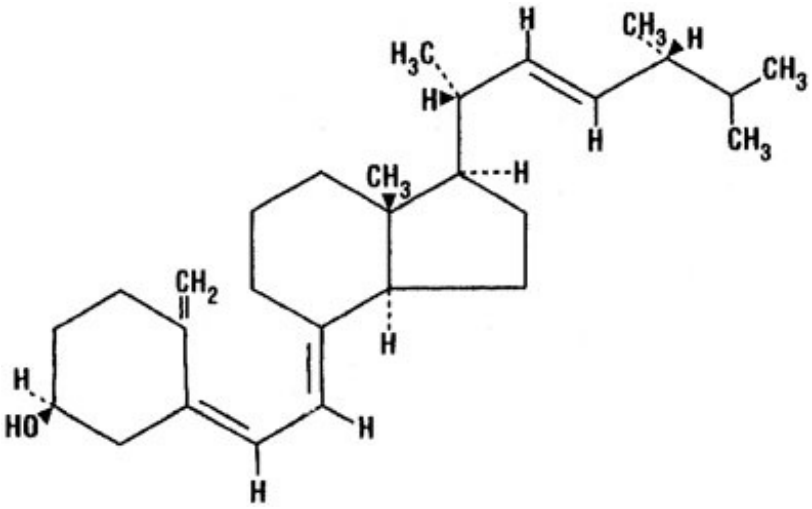
Ergocalciferol is a white, colorless crystal, insoluble in water, soluble in organic solvents, and slightly soluble in vegetable oils. It is affected by air and by light. Ergosterol or provitamin D_2 is found in plants and yeast and has no antirachitic activity.

There are more than 10 substances belonging to a group of steroid compounds, classified as having vitamin D or antirachitic activity.

One USP Unit of vitamin D_2 is equivalent to one International Unit (IU), and 1 mcg of vitamin D_2 is equal to 40 IU.

Each softgel capsule, for oral administration, contains Ergocalciferol, USP 1.25 mg (equivalent to 50,000 USP units of Vitamin D), in an edible vegetable oil.

Ergocalciferol, also called vitamin D_2 ,is 9, 10-secoergosta-5, 7,10(19),22-tetraen-3-ol,(3β,5Z,7E,22E)-; ($C_{28}H_{44}O$) with a molecular weight of 396.65, and has the following structural formula:



Chemical Structure

Inactive Ingredients: D and C Yellow #10, FD and C Blue #1, Gelatin, Glycerin, Purified Water, Refined Soybean Oil.

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. Parathyroid hormone is responsible for the regulation of this metabolism in the kidneys.

INDICATIONS AND USAGE

Ergocalciferol Capsules, USP are indicated for use in the treatment of hypoparathyroidism, refractory rickets, also known as vitamin D resistant rickets, and familial hypophosphatemia.

CONTRAINDICATIONS

Ergocalciferol Capsules, USP 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.

Keep out of the reach of children.

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.

The LD_{50} in animals is unknown. The toxic oral dose of ergocalciferol in the dog is 4 mg/kg.

DOSAGE AND ADMINISTRATION

THE RANGE BETWEEN THERAPEUTIC AND TOXIC DOSES IS NARROW.

Vitamin D Resistant Rickets: 12,000 to 500,000 USP units daily.

Hypoparathyroidism: 50,000 to 200,000 USP units daily concomitantly with calcium lactate 4 g, six times per day.

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.

HOW SUPPLIED

Each green, oval softgel capsule is imprinted with A3 and contains 1.25 mg (50,000 USP units vitamin D) of ergocalciferol, USP.

Bottles of 100 Softgel Capsules (NDC 51991-604-01).

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

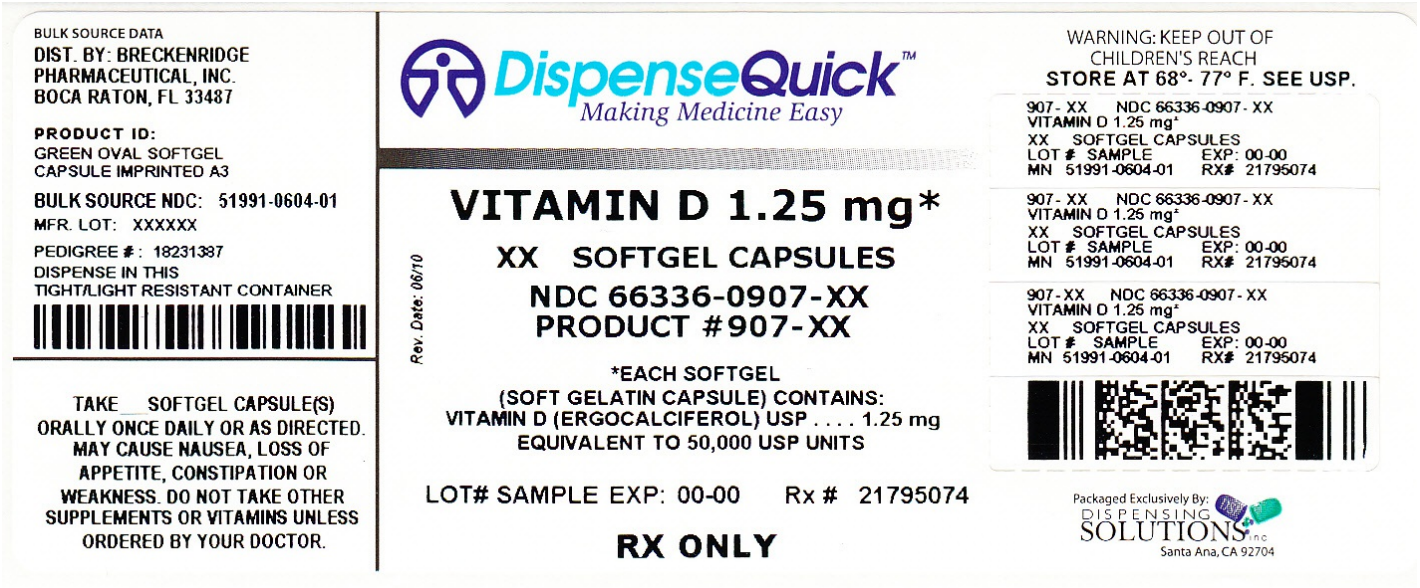
Protect from light and moisture.

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

Manufactured by: Swiss Caps AG
Kirchberg, Switzerland
Distributed by: Breckenridge Pharmaceutical, Inc.
Boca Raton, FL 33487

Rev. 04/09

PRINCIPAL DISPLAY PANEL



NDC 66336-0907-XX
NDC 66336-0907-06
NDC 66336-0907-44

ERGOCALCIFEROL

ergocalciferol capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:66336-907(NDC:51991-604)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Ergocalciferol (UNII: VS041H42XC) (Ergocalciferol - UNII:VS041H42XC)	Ergocalciferol	1.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C Yellow No. 10 (UNII: 35SW5USQ3G)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Soybean Oil (UNII: 241ATL177A)	

Product Characteristics			
Color	green	**Score**	no score
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	A3
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66336-907-06	6 in 1 BOTTLE		
2	NDC:66336-907-44	4 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040833	08/17/2009	

Labeler - Dispensing Solutions, Inc. (066070785)

Registrant - PSS World Medical, Inc. (101822682)

Establishment

Name	Address	ID/FEI	Business Operations
Dispensing Solutions, Inc.		066070785	relabel, repack

Revised: 2/2012 Dispensing Solutions, Inc.