REVESTA- revesta 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.

Revesta

Cholecalciferol Capsules

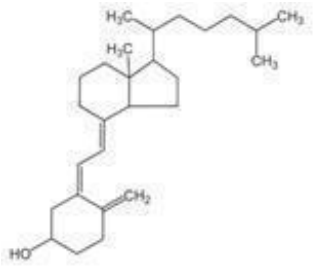
Rx Only

DESCRIPTION

Revesta 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.

Revesta 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): 5750IU

Each capsule contains the following inactive ingredients: soybean oil, gelatin (bovine), yellow wax, glycerin, deionized water, lecithin, titanium dioxide, FD&C Blue #1.

INDICATIONS AND USAGE

Revesta 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. Revesta 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

Revesta capsules are supplied as blue capsules imprinted in white ink “330”, dispensed in HDPE plastic bottles of 30ct.

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

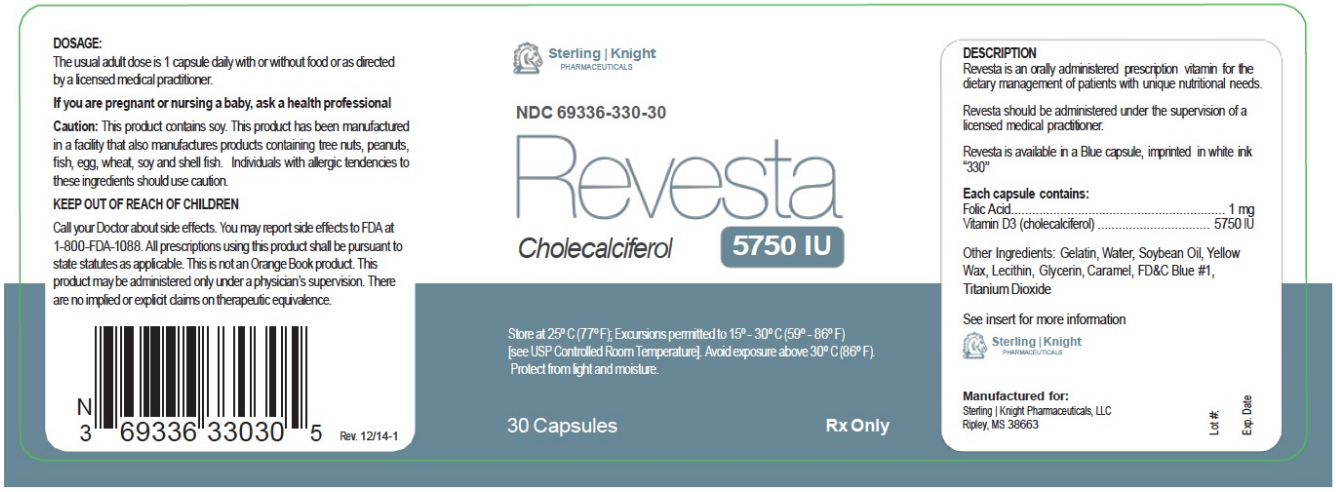
Reserved for Professional Recommendation

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.

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



REVESTA

revesta capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69336-330
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	5750 [iU]
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
SOYBEAN OIL (UNII: 241ATL177A)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	22mm
Flavor		**Imprint Code**	330
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69336-330-30	30 in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	10/13/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/13/2016	

Labeler - Sterling Knight Pharmaceuticals,LLC (079556942)

Establishment

Name	Address	ID/FEI	Business Operations
Sterling Knight Pharmaceuticals,LLC		079556942	manufacture(69336-330) , label(69336-330)

Revised: 12/2019 Sterling Knight Pharmaceuticals,LLC