

DURACHOL- durachol 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.

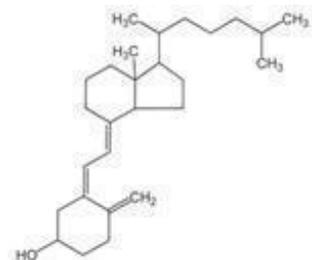
Durachol

DESCRIPTION

Durachol 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.

Durachol 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, cellulose, magnesium stearate, silica, FD&C Red #3, FD&C Yellow # 6.

INDICATIONS AND USAGE

Durachol 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. Durachol 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

Durachol capsules are supplied as orange capsules printed with Durachol 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. 10/14-3

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. 12/14-1



NDC 69336-300-30

Durachol
Cholecalciferol **3775 IU**

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

Rx Only

DESCRIPTION

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

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

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

Each capsule contains:

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

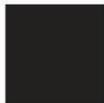
Other Ingredients: Gelatin, Water, Soybean Oil, Yellow Wax, Lecithin, Glycerin, FD&C Red #40, FD&C Yellow #5, Titanium Dioxide.

See insert for more information



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

Lot #:
Exp. Date



BLACK



PMS 1505

DURACHOL

durachol capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:69336-300
Route of Administration	Oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHOLECALCIFEROL (UNII: 1C6 V77QF41) (CHOLECALCIFEROL - UNII:1C6 V77QF41)	CHOLECALCIFEROL	3775 [iU]
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SOYBEAN OIL (UNII: 241ATL177A)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
GLYCERIN (UNII: PDC6A3C0OX)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics

Color	orange	Score	no score
Shape	capsule	Size	22mm
Flavor		Imprint Code	Durachol
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69336-300-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/16/2014	

Labeler - Sterling Knight Pharmaceuticals,LLC (079556942)

Revised: 1/2015

Sterling Knight Pharmaceuticals,LLC