

ANIMI-3 WITH VITAMIN D - folic acid, cholecalciferol, pyridoxine hydrochloride, cyanocobalamin, omega-3 fatty acids, doconexent, icosapent capsule
PBM Pharmaceuticals, Inc

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.

Animi-3 with Vitamin D

Package Insert

Animi-3® with Vitamin D

Each Capsule Contains:

Folic Acid (Vitamin B9)	1mg
Cholecalciferol (Vitamin D3)	1000IU
Pyridoxine Hydrochloride (Vitamin B6)	12.5mg
Cyanocobalamin (Vitamin B12)	500mcg
Omega-3 Acids	500mg
-Docosahexaenoic Acid (DHA)	350mg
-Eicosapentaenoic Acid (EPA)	35mg
Phytosterols (Plant Sterols)	200mg

Patent Pending

Rx Only

Description

Animi-3® with Vitamin D Capsules are intended for oral administration.

Each Capsule Contains: 1mg Vitamin B-9 (Folic Acid USP), 1000IU Vitamin D-3 (Cholecalciferol), 12.5mg Vitamin B-6 (Pyridoxine Hydrochloride, USP), 500mcg vitamin B-12 (Cyanocobalamin, USP), Pharmaceutical Grade omega-3 Fish Oil providing 500mg Omega-3 Acids; including 350mg Docosahexaenoic Acid (DHA) and 35mg Eicosapentaenoic Acid (EPA) and 200mg Plant Sterols (Phytosterols).

Also Contains: Bleached Lecithin NF, Ascorbic Acid USP, Mixed Tocopherols NF, Ascorbyl Palmitate NF and a soft shell capsule (which contains; Gelatin USP, Glycerin NF, Titanium Dioxide USP, FD and C Red #40, FD and C Yellow #6 and USP Purified Water).

Indication

Animi-3® with Vitamin D Capsules are indicated for improving nutritional status in conditions requiring Essential Fatty Acids, Vitamin B12, Vitamin B6, Vitamin D3 and Folic Acid supplementation.

This product is contraindicated in patients with a known hyper-sensitivity to any of the ingredients.

Warning

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including an increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anti-coagulants and in those known to have inherited or acquired bleeding diathesis.

Warning

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 1.0mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Pregnancy and Lactation

The safety of phytosterols has not been studied in pregnant or breastfeeding women. There is no evidence that dietary intakes of naturally occurring phytosterols, such as those consumed by vegetarian women, adversely affects pregnancy or lactation.

Adverse Reactions

Allergic sensitization has been reported following oral, enteral and parenteral administration of folic acid.

Dosage and Administration

Adults – One capsule per day or as directed by a physician.

How Supplied

Animi-3® with Vitamin D supplied as orange opaque oblong capsules. Each capsule is imprinted with “Animi-3D” in black opacode. Animi-3® with Vitamin D Capsules are available in bottles of 60 capsules (NDC 66213-542-60).

Keep out of reach of children.

Dispense in a well-closed, tight light-resistant container as defined in the USP using a child-resistant closure.

Storage Conditions:

Store at 20-25°C (68-77°F). See USP Controlled Room Temperature. Protect from light and moisture.

PBM Pharmaceuticals, Inc.

Charlottesville, VA 22902

Rev. 0411

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NDC 66213-542-60 60 Capsules

Animi 3D with Vitamin D

Folic Acid (Vitamin B-9) 1 mg
Cholecalciferol (Vitamin D-3) 1000 IU
Pyridoxine Hydrochloride (Vitamin B-6) 12.5 mg
Cyanocobalamin (Vitamin B-12) 500 mcg
Omega 3 Acids 500 mg
– Docosahexaenoic Acid (DHA) 350 mg
– Eicosapentaenoic Acid (EPA) 35 mg

Phytosterols (Plant Sterols) 200 mg

Rx Only

Animi 3D with Vitamin D label rev 1210 152.476mm-wide x 48.312mm-high 6p 03-29-11 bt
 pms 1935, pms 1655, pms 7461, Black



ANIMI-3 WITH VITAMIN D

folic acid, cholecalciferol, pyridoxine hydrochloride, cyanocobalamin, omega-3 fatty acids, doconexent, icosapent capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66213-542
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	1000 [iU]
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	12.5 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	500 ug
Omega-3 Fatty Acids (UNII: 71M78END5S) (Omega-3 Fatty Acids - UNII:71M78END5S)	Omega-3 Fatty Acids	500 mg
Doconexent (UNII: ZAD9OKH9JC) (Doconexent - UNII:ZAD9OKH9JC)	Doconexent	250 mg
Icosapent (UNII: AAN7QOV9EA) (Icosapent - UNII:AAN7QOV9EA)	Icosapent	35 mg
Soy Sterol (UNII: PL360EPO9J) (Soy Sterol - UNII:PL360EPO9J)	Soy Sterol	200 mg

Inactive Ingredients

Ingredient Name	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Alpha-Tocopherol (UNII: H4N855PNZ1)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	

Gelatin (UNII: 2G86QN327L)	
Glycerin (UNII: PDC6A3C0OX)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
Water (UNII: 059QF0KO0R)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
FD&C Yellow No. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL (Capsule)	Size	20mm
Flavor		Imprint Code	Animi;3D
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66213-542-60	60 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/01/2011	

Labeler - PBM Pharmaceuticals, Inc (785470050)

Establishment

Name	Address	ID/FEI	Business Operations
International Vitamin Corporation		964464114	manufacture