

ANIMI-3® - Rev. 4/11 -Rx Only

Each Capsule contains:

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

U.S. Patent No: 8,075,910

Rx Only

Description

Animi-3® Capsules are intended for oral administration. Each Capsule Contains: 1 mg Vitamin B-9 (Folic Acid USP), 12.5 mg Vitamin B-6 (Pyridoxine Hydrochloride, USP), 500 mcg Vitamin B-12 (Cyanocobalamin, USP), Pharmaceutical Grade Omega-3 Fish Oil providing 500 mg Omega-3 Acids; including 350 mg Docosahexaenoic Acid (DHA) and 35 mg Eicosapentaenoic Acid (EPA) and 200 mg 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&C Red 40 and USP Purified Water).

Indication

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

Contraindications

This product is contraindicated in patients with a known hypersensitivity 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 1.0 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.



Animi-3®

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® supplied as red opaque oblong Capsules. Each Capsule is imprinted with "Animi-3" in black opacode. Animi-3® Capsules are available in bottles of 60 capsules (NDC 66213-541-60).

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.

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