Prenate Restore®

Rx Only Dietary Supplement

DESCRIPTION: PRENATE RESTORE® is a prescription postnatal vitamin dietary supplement that contains probiotics, DHA, and advanced calcium. Each dark blue softgel is imprinted with “Omega Rx” on one side and blank on the other.

Supplement Facts

Serving Size: 1 Softgel
Servings Per Container: 30

Each Softgel Contains	Amount Per Serving	% Daily Value	% Daily Value for Pregnant & Lactating Women
Calories	10		
Total Fat	1 g	1%*	1%*
Saturated Fat	0 g	0%*	0%*
Trans Fat	0 g	†	†
Vitamin C (as ascorbic acid)	85 mg	94%	71%
Vitamin D (as cholecalciferol)	25 mcg	125%	167%
Vitamin E (as dl-alpha tocopheryl acetate)	4.5 mg	30%	24%
Vitamin B6 (as pyridoxine HCl)	25 mg	1471%	1250%
Folate 1.1 mg Quatrefolic® (as (6S)-5-methyltetrahydrofolate glucosamine salt (equivalent to 600 mcg of folic acid) and folic acid USP 400 mcg)	1700 mcg DFE	425%	283%
Vitamin B12 (as cyanocobalamin)	12 mcg	500%	429%
Biotin	500 mcg	1667%	1429%
Calcium (as a blend of Formical® (calcium formate) and calcium carbonate)	160 mg	12%	12%
Iron (as a blend of Sumalate® (ferrous asparto glycinate) and ferrous fumarate)	27 mg	150%	100%
Magnesium (as magnesium oxide)	45 mg	11%	11%
Bacillus Coagulens (as Lactospore®) 150 Million CFU	10 mg	†	†
Docosahexaenoic Acid (DHA)	400 mg	†	†

† Daily Value (DV) not established.
* Percent Daily Values (DV) are based on a 2,000 calorie diet

OTHER INGREDIENTS: Beeswax, palm shortening, and soy lecithin. Gelatin capsule (FD&C Blue #1, FD&C Red #3, gelatin, glycerin, purified water, sorbitol, and titanium dioxide).

INDICATIONS: PRENATE RESTORE® s a multivitamin/multimineral fatty acid dietary supplement indicated for use in improving the nutritional status of women during the postnatal period for both lactating and non-lactating mothers.

CONTRAINDICATIONS: PRENATE RESTORE® 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 (such as DHA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

PRECAUTIONS: 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 progress.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic test (e.g. troponin) and hormone tests, and may lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. **Keep this product out of reach of children.** In case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION: One softgel daily, or as directed by a physician.

HOW SUPPLIED: Bottles of 30 softgels (75854-308-30)

The listed product number is not a National Drug Code. Instead, Avion Pharmaceuticals has assigned a product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

STORAGE: Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP Controlled Room Temperature.]

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

MANUFACTURED FOR:
Avion Pharmaceuticals, LLC
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1-888-61-AVION
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Sumalate® is a registered trademark and is covered by one or more claims of U.S. Patent Nos. 8,007,846 and 8,425,956, all owned by Albion Laboratories, Inc.

LactoSpore® is a registered trademark of Sabinsa Corporation.