

# Prenate mini<sup>®</sup>

## Rx Only Dietary Supplement

**DESCRIPTION:** PRENATE MINI<sup>®</sup> is a prescription prenatal/postnatal multivitamin/mineral/essential fatty acid softgel. Each oval softgel is teal green in color and imprinted with "Mini".

## Supplement Facts

Serving Size: 1 Softgel

Amount per Serving:		% Daily Value	% Daily Value
			(Pregnant & Lactating Women)
Vitamin C (as ascorbic acid)	60 mg	100%	100%
Vitamin D3 (as cholecalciferol)	1000 IU	250%	250%
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU	33%	33%
Vitamin B6 (as pyridoxine HCl)	26 mg	1300%	1040%
Folate (as (6S)-N5-methyl-tetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg))	1 mg	250%	125%
Vitamin B12 (as cyanocobalamin)	13 mcg	217%	163%
Biotin	280 mcg	93%	93%
Calcium (as calcium carbonate)	80 mg	8%	6%
Iron (as Sumalate <sup>®</sup> (ferrous asparto glycinate) and carbonyl iron)	18 mg	100%	100%
Iodine (as potassium iodide)	150 mcg	100%	100%
Magnesium (as magnesium oxide)	25 mg	6%	6%
Docosahexaenoic acid (DHA)	350 mg	†	†
Blueberry extract (vaccinium spp.)	25 mg	†	†

† Daily Value (DV) not established.

Contains fish oil and soy. Contains FD&C Yellow No. 5 (tartrazine) as a color additive.

**OTHER INGREDIENTS:** Bovine gelatin, FD&C Blue #1, FD&C Yellow #5, fish (tuna) oil, glycerin, purified water, soy lecithin, titanium dioxide, vegetable shortening and yellow beeswax.

**INDICATIONS:** PRENATE MINI<sup>®</sup> is a multivitamin/multimineral fatty acid dietary supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. PRENATE MINI<sup>®</sup> can also be beneficial in improving the nutritional status of women prior to conception.

**CONTRAINDICATIONS:** PRENATE MINI<sup>®</sup> 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. This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

**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:** Before, during and/or pregnancy, one softgel daily or as directed by a physician.

**HOW SUPPLIED:** Bottles of 30 softgels (75854-315-30). 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.]

**Avion**  
PHARMACEUTICALS

### MANUFACTURED FOR:

Avion Pharmaceuticals, LLC  
Alpharetta, GA 30005  
1-888-61-AVION  
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Sumalate<sup>®</sup> is a registered trademark of Albion Laboratories, Inc., covered by one or more claims of U.S. Patent Nos. 6,716,814; 8,007,846; and 8,425,956.

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**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.**

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