Prenate Elite®

Rx Only Dietary Supplement

DESCRIPTION: PRENATE ELITE® is a white, oval, oil- and water-soluble, multivitamin/multimineral, film-coated tablet debossed with "PN" on one side and blank on the other. Contains no ingredient made from gluten-containing grain (wheat, barley, or rye).

Supplement Facts

Serving Size: 1 Tablet
Servings Per Container: 30

Each Tablet Contains	Amount Per Serving	% Daily Value	% Daily Value for Pregnant & Lactating Women
Vitamin A (as beta-carotene)	780 mcg RAE	87%	60%
Vitamin C (as ascorbic acid)	75 mg	83%	63%
Vitamin D (as cholecalciferol)	15 mcg	75%	100%
Vitamin E (as dl-alpha tocopheryl acetate)	18 mg	120%	95%
Thiamin (as thiamine mononitrate)	3 mg	250%	214%
Riboflavin	3.5 mg	269%	219%
Niacin (as niacinamide)	21 mg	131%	117%
Vitamin B6 (as pyridoxine HCl)	21 mg	1235%	1050%
Folate (as 1.11 mg of (6S)-N5-methyltetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid,USP 400 mcg)	1700 mcg DFE	425%	283%
Vitamin B12 (as cyanocobalamin)	13 mcg	542%	464%
Biotin	330 mcg	1100%	943%
Calcium (as calcium formate) Formical®	160 mg	12%	12%
Iron (as ferrous asparto glycinate) Sumalate®	20 mg	111%	74%
Iodine (as potassium iodide)	150 mcg	100%	52%
Magnesium (as magnesium oxide)	25 mg	6%	6%
Zinc (as zinc oxide)	15 mg	136%	115%
Copper (as cupric oxide)	1.5 mg	167%	115%

OTHER INGREDIENTS: Croscarmellose Sodium, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide, Stearic Acid. Film Coating (Hypromellose, Titanium Dioxide, Triacetin).

INDICATIONS: PRENATE ELITE® 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.

CONTRAINDICATIONS: PRENATE ELITE® is contraindicated in patients with a known hypersensitivity to any of the ingredients.

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

HOW SUPPLIED: Bottles of 30 tablets. (75854-314-30)

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
Alpharetta, GA 30005
1-888-61-AVION
4290-v1 Rev. 06/26

PRENATE®, ELITE®, and AVION® are registered trademarks of Avion Pharmaceuticals, LLC. All rights reserved.

Formical® is a registered trademark of Nephro-Tech 1, LLC

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.