

**PRENATE ELITE- .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, 5-methyltetrahydrofolic acid, calcium formate, ferrous asparto glycinate, cyanocobalamin, biotin, potassium iodide, magnesium oxide, zinc oxide and cupric oxide tablet, coated  
Avion Pharmaceuticals, LLC**

*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.*

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**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.

# Supplement Facts

Serving Size: 1 Tablet

Amount per Serving:		% Daily Value	% Daily Value (Pregnant & Lactating Women)
Vitamin A (100% as beta-carotene)	2600 IU	52%	33%
Vitamin C (as ascorbic acid)	75 mg	125%	125%
Vitamin D3 (as cholecalciferol)	600 IU	150%	150%
Vitamin E (as dl-alpha tocopheryl acetate)	40 IU	133%	133%
Thiamin (as thiamine mononitrate)	3 mg	200%	176%
Riboflavin	3.5 mg	206%	175%
Niacinamide	21 mg	105%	105%
Vitamin B6 (as pyridoxine HCl)	21 mg	1050%	840%
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))	1 mg	250%	125%
Calcium (as calcium formate) Formical®	155 mg	16%	12%
Iron (as ferrous asparto glycinate) Sumalate®	20 mg	111%	111%
Vitamin B12 (as cyanocobalamin)	13 mcg	217%	163%
Biotin	330 mcg	110%	110%
Iodine (as potassium iodide)	150 mcg	100%	100%
Magnesium (as magnesium oxide)	25 mg	6%	6%
Zinc (as zinc oxide)	15 mg	100%	100%
Copper (as cupric oxide)	1.5 mg	75%	75%

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

**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 B<sub>12</sub> 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.

**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.

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

**MANUFACTURED FOR:**

Avion Pharmaceuticals, LLC

Alpharetta, Georgia 30005

1-888-61-AVION

Rev. 0519-01

Formical<sup>®</sup> is a registered trademark of Nephro-Tech 1, LLC, covered by one or more claims of U.S. Patent No. 6,528,542.

Sumalate<sup>®</sup> is a registered trademark of Albion Laboratories, Inc., covered by one or more claims of U.S. Patent Nos. 5,516,925, 6,716,814, 8,007,846, and 8,425,956.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

75854-314-30

***Prenate Elite***<sup>®</sup>

PRENATAL VITAMINS-FILM-COATED TABLETS

**GLUTEN FREE**

**Rx Only**

**Dietary Supplement**

**30 Tablets**

Avion  
PHARMACEUTICALS



75854-314-30

PEEL HERE ▶



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PRENATAL VITAMINS—FILM-COATED TABLETS

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**KEEP OUT OF REACH OF CHILDREN.**

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**MANUFACTURED FOR:**  
Avion Pharmaceuticals, LLC  
Alpharetta, Georgia 30005 1-888-61-AVION  
Rev. 0419-01

**Lot #:**  
**Exp:**

## PRENATE ELITE

.beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, 5-methyltetrahydrofolic acid, calcium formate, ferrous asparto glycinate, cyanocobalamin, biotin, potassium iodide, magnesium oxide, zinc oxide and cupric oxide tablet, coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75854-314
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>.BETA.-CAROTENE</b> (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	2600 [iU]
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	75 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	600 [iU]
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	40 [iU]
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.5 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	21 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	21 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	400 ug
<b>5-METHYLTETRAHYDROFOLIC ACID</b> (UNII: TYK22LML8F) (5-METHYLTETRAHYDROFOLIC ACID - UNII:TYK22LML8F)	5-METHYLTETRAHYDROFOLIC ACID	600 ug
<b>CALCIUM FORMATE</b> (UNII: NP3JD65NPY) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	155 mg
<b>FERROUS ASPARTO GLYCINATE</b> (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	20 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug

<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	330 ug
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
<b>MAGNESIUM OXIDE</b> (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 mg
<b>CUPRIC OXIDE</b> (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1.5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>POWDERED CELLULOSE</b> (UNII: SMD1X3XO9M)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PN
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-314-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/05/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/05/2014	

**Labeler** - Avion Pharmaceuticals, LLC (040348516)

### Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-314)