

**PRENATE ESSENTIAL- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, 5-methyltetrahydrofolic acid, cyanocobalamin, biotin, calcium formate, ferrous asparto glycinate, potassium iodide, magnesium oxide, doconexent and icosapent capsule, gelatin 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.*

-----

**PRENATE ESSENTIAL®**

*Rx prenatal vitamin & DHA*

**Rx Only**

**DESCRIPTION:** PRENATE ESSENTIAL® is a prescription prenatal/postnatal multivitamin/mineral/essential fatty acid softgel. Each softgel is green in color, opaque, and imprinted with "Prenate" on one side and blank on the other.

# Supplement Facts

Serving Size: 1 Softgel

Amount per Serving:		% Daily Value	% Daily Value (Pregnant & Lactating Women)
Vitamin C (as ascorbic acid)	90 mg	150%	150%
Vitamin D <sub>3</sub> (as cholecalciferol)	220 IU	55%	55%
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU	33%	33%
Vitamin B <sub>6</sub> (as pyridoxine HCl)	26 mg	1300%	1040%
Folate (as ((6S)-N <sup>5</sup> -methyltetrahydrofolic acid calcium salt (molar equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1 mg	250%	125%
Vitamin B <sub>12</sub> (as cyanocobalamin)	13 mcg	217%	163%
Biotin	280 mcg	93%	93%
Calcium (as Formical <sup>®</sup> (calcium formate))	155 mg	16%	12%
Iron (as Sumalate <sup>®</sup> (ferrous asparto glycinate))	18 mg	100%	100%
Iodine (as potassium iodide)	150 mcg	100%	100%
Magnesium (as magnesium oxide)	50 mg	13%	11%
Docosahexaenoic Acid (DHA)	300 mg	†	†
Eicosapentaenoic Acid (EPA)	40 mg	†	†

† Daily Value (DV) not established.

PRENATE ESSENTIAL<sup>®</sup> contains fish oil and soy.

**OTHER INGREDIENTS:** Capsule gelatin (gelatin, sorbitol, glycerin, purified water, turmeric, and sodium copper chlorophyllin), soy lecithin, yellow beeswax and soybean oil.

**INDICATIONS:** PRENATE ESSENTIAL<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 ESSENTIAL<sup>®</sup> can also be beneficial in improving the nutritional status of women prior to conception

**CONTRAINDICATIONS:** PRENATE ESSENTIAL<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 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 softgel daily or as directed by a physician.

**HOW SUPPLIED:** Bottles of 30 softgels (75854-313-30).

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.]

**MANUFACTURED FOR:** Avion Pharmaceuticals, LLC

Atlanta, GA 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**

**75854-313-30**

***PRENATE ESSENTIAL***<sup>®</sup>

***Rx prenatal vitamin & DHA***

• **Key vitamins, minerals, and DHA support nutrition**

**GLUTEN FREE**

**Rx Only**

# Dietary Supplement

30 Softgels

## PRENATE ESSENTIAL

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, 5-methyltetrahydrofolic acid, cyanocobalamin, biotin, calcium formate, ferrous asparto glycinate, potassium iodide, magnesium oxide, doconexent and icosapent capsule, gelatin coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75854-313
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ICOSAPENT</b> (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	40 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	90 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	220 [IU]
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [IU]
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	26 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>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug
<b>BIOTIN</b> (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	280 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	18 mg
<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	50 mg		
<b>DOCONEXENT</b> (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg		
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>		<b>Strength</b>		
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)				
WHITE WAX (UNII: 7G1J5DA97F)				
WATER (UNII: 059QF0KO0R)				
SOYBEAN OIL (UNII: 241ATL177A)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
<b>Product Characteristics</b>				
<b>Color</b>	green, yellow (opaque)	<b>Score</b>	no score	
<b>Shape</b>	OVAL	<b>Size</b>	24mm	
<b>Flavor</b>		<b>Imprint Code</b>	Prenate	
<b>Contains</b>				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:75854-313-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2014	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
unapproved drug other		07/18/2014		

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

### Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-313)