

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%
VitaminD ₃ (as cholecalciferol)	220 IU	55%	55%
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU	33%	33%
Vitamin B6 (as pyridoxine HCl)	26 mg	1300%	1040%
Folate (as ((6S)-N5-methyltetrahydrofolic acid calcium salt (molar equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1 mg	250%	125%
Vitamin B ₁₂ (as cyanocobalamin)	13 mcg	217%	163%
Biotin	280 mcg	93%	93%
Calcium (as Formical® (calcium formate))	155 mg	16%	12%
Iron (as Sumalate® (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[®] 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[®] 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[®] can also be beneficial in improving the nutritional status of women prior to conception

CONTRAINDICATIONS: PRENATE ESSENTIAL[®] 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.

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[®] is a registered trademark of Nephro-Tech 1, LLC, covered by one or more claims of U.S. Patent No. 6,528,542.

Sumalate[®] 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®

Rx prenatal vitamin & DHA

- Key vitamins, minerals, and DHA support nutrition

GLUTEN FREE

Rx Only

Dietary Supplement

30 Softgels

Avion
PHARMACEUTICALS

75854-313-30

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Rx prenatal vitamin & DHA

• Key vitamins, minerals, and DHA support nutrition

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KEEP OUT OF REACH OF CHILDREN.

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
Alpharetta, Georgia 30005 1-888-61-AMON
Rev. 0419-01

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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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	40 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	90 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	220 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [iU]
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	26 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	400 ug
5-METHYLTETRAHYDROFOLIC ACID (UNII: TYK22LML8F) (5-METHYLTETRAHYDROFOLIC ACID - UNII:TYK22LML8F)	5-METHYLTETRAHYDROFOLIC ACID	600 ug

CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	280 ug
CALCIUM FORMATE (UNII: NP3JD65NPY) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	155 mg
FERROUS ASPARTO GLYCINATE (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	18 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	50 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	300 mg

Inactive Ingredients

Ingredient Name	Strength
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)	

Product Characteristics

Color	green, yellow (opaque)	Score	no score
Shape	OVAL	Size	24mm
Flavor		Imprint Code	Prenate
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-313-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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)