

PRENATE MINI- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium carbonate, ferrous asparto glycinate, iron, potassium iodide, magnesium oxide, doconexent and lowbush blueberry 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 Mini[®] 75854-0315-30

Rx Only Dietary Supplement

DESCRIPTION: PRENATE MINI[®] 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® (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[®] 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[®] can also be beneficial in improving the nutritional status of women prior to conception.

CONTRAINDICATIONS: PRENATE MINI[®] 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 after pregnancy, one softgel daily or as directed by a physician.

HOW SUPPLIED: Bottles of 30 softgels (75854-0315-30). 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

Alpharetta, GA 30005

1-888-61-AVION

Rev. 0519-01

Sumalate[®] 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.

PRENATE[®] is a registered trademark of Avion Pharmaceuticals, LLC. All rights reserved.

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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

75854-0315-30

Rx Only Dietary Supplement

Prenate mini®

A small, easy-to-swallow softgel with complete prenatal nutrition support, including 350 mg of DHA

30 Softgels

SUGAR FREE

GLUTEN FREE

LACTOSE FREE

Avion

PHARMACEUTICALS



PRENATE MINI

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium carbonate, ferrous asparto glycinate, iron, potassium iodide, magnesium oxide, doconexent and lowbush blueberry capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75854-315
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	1000 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [iU]
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	26 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	400 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	280 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	80 mg
FERROUS ASPARTO GLYCINATE (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	9 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	9 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	25 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	350 mg
LOWBUSH BLUEBERRY (UNII: G90PX41VP0) (ICOSAPENT - UNII:AAN7QOV9EA)	LOWBUSH BLUEBERRY	25 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug

Inactive Ingredients

Ingredient Name	Strength
FISH OIL (UNII: XGF7L72M0F)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
WATER (UNII: 059QF0K00R)	
CORN OIL (UNII: 8470G57WFM)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	green (teal green)	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	Mini
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-315-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/18/2014	

Labeler - Avion Pharmaceuticals, LLC (040348516)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-315)

Revised: 7/2019

Avion Pharmaceuticals, LLC