

PRENATE DHA- ascorbic acid, cholecalciferol, .alpha.-tocopherol, dl-, folic acid, pyridoxine hydrochloride, cyanocobalamin, calcium formate, ferrous asparto glycinate, magnesium oxide and doconexent 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 DHA[®]

Rx Only Dietary Supplement

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

Supplement Facts			
Serving Size: 1 Softgel			
Amount per Serving:		% Daily Value	% Daily Value for Pregnant & Lactating Women
Vitamin C (as ascorbic acid)	90 mg	150%	150%
Vitamin D3 (as cholecalciferol)	400 IU	100%	100%
Vitamin E (as dl-alpha tocopherol acetate)	40 IU	133%	133%
Folate (as (6S)-N5-methyltetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1 mg	250%	125%
Vitamin B6 (as pyridoxine HCl)	26 mg	1300%	1040%
Vitamin B12 (as cyanocobalamin)	25 mcg	417%	313%
Calcium (as Formical [®] (calcium formate))	155 mg	16%	12%
Iron (as Sumalate [®] (ferrous asparto glycinate))	18 mg	100%	100%
Magnesium (as magnesium oxide)	50 mg	13%	11%
Docosahexaenoic Acid (DHA)	300 mg	†	†

† Daily Value (DV) not established.

PRENATE DHA[®] contains fish oil and soy.

OTHER INGREDIENTS: Gelatin capsule (FD&C Blue #1, FD&C Red #3, gelatin, glycerin,

purified water, sorbitol and titanium dioxide), soybean oil, soy lecithin, and white beeswax.

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

CONTRAINDICATIONS: PRENATE DHA[®] 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 (75854-312-30).

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

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.

PRENATE[®] is a registered trademark of Avion Pharmaceuticals, LLC. Under license from Avion Pharmaceuticals, LLC.

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Rev. 0519-02

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

75854-312-30

Prenate DHA[®]

Rx prenatal vitamin & DHA

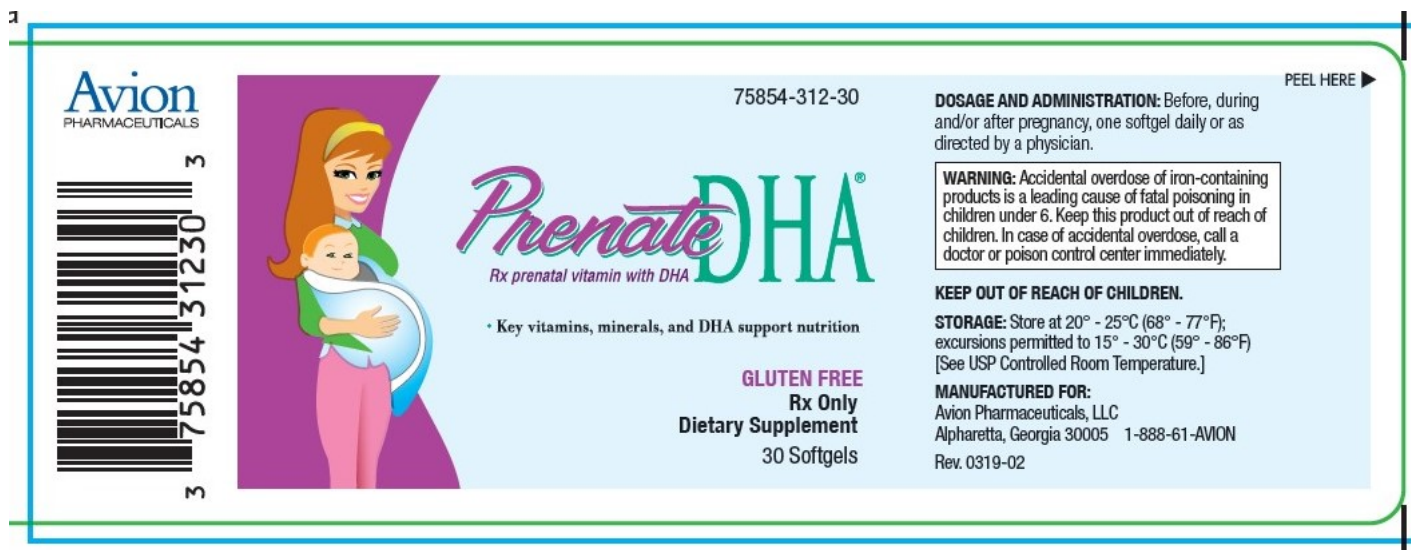
- Key vitamins, minerals, and DHA support nutrition

GLUTEN FREE

Rx Only

Dietary Supplement

30 Softgels



PRENATE DHA

ascorbic acid, cholecalciferol, .alpha.-tocopherol, dl-, folic acid, pyridoxine hydrochloride, cyanocobalamin, calcium formate, ferrous asparto glycinate, magnesium oxide and doconexent capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75854-312
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	90 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	40 [iU]
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	26 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	25 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
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)	
SOYBEAN OIL (UNII: 241ATL177A)	
WHITE WAX (UNII: 7G1J5DA97F)	
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	

Product Characteristics			
Color	blue (opaque)	Score	no score
Shape	OVAL	Size	24mm
Flavor		Imprint Code	301
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-312-30	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		06/05/2014	

other		06/05/2014	
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Labeler - Avion Pharmaceuticals, LLC (040348516)

Registrant - Avion Pharmaceuticals, LLC (965450542)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-312)

Revised: 1/2024

Avion Pharmaceuticals, LLC