PRENATE RESTORE- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, folic acid, pyridoxine hydrochloride, cyanocobalamin, biotin, calcium carbonate, ferrous fumarate, magnesium oxide, lactic acid 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®* Restore**

Rx postnatal vitamin with probiotics, DHA and chelated iron

Rx Only Dietary Supplement

DESCRIPTION: PRENATE ® Restore is a prescription postnatal vitamin dietary supplement that contains probiotics, DHA and advanced calcium. Each dark blue softgel is imprinted with Omega Rx 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)	85 mg	142%	142%
Vitamin D3 (as Cholecalciferol)	1000 IU	250%	250%
Vitamin E (as dl-Alpha Tocopheryl Acetate)	10 IU	33%	33%
Folate (as 1.11 mg of (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 B6 (as Pyridoxine HCl)	25 mg	1250%	1000%
Vitamin B12 (as Cyanocobalamin)	12 mcg	200%	150%
Biotin	500 mcg	167%	167%
Calcium (as a blend of Calcium Formate–Formical® and Calcium Carbonate)	155 mg	16%	12%
Iron (as a blend of ferrous asparto glycinate–Sumalate® and Ferrous Fumarate)	27 mg	150%	150%
Magnesium (as Magnesium Oxide)	45 mg	11%	10%
Bacillus Coagulans (as Lactospore®) 150 Million CFU	10 mg	†	†
Docosahexaenoic Acid (DHA)	400 mg	†	†

† Daily Value (DV) not established.

OTHER INGREDIENTS: Gelatin capsule (gelatin, sorbitol, glycerin, purified water, FD&C Blue # 1, titanium dioxide, and FD&C Red # 3), beeswax, soy lecithin, and palm shortening.

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

CONTRAINDICATIONS: PRENATE ® Restore 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: One softgel daily, or as directed by a physician.

HOW SUPPLIED: Bottles of 30 softgels (75854-308-30). 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.]

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

MANUFACTURED FOR:

Avion Pharmaceuticals, LLC

Alpharetta, 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.

LactoSpore ® is a registered trademark of Sabinsa Corporation.

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.

PRINCIPAL DISPLAY PANEL - 30 Softgel label

75854-308-30

***PRENATE* ® Restore**

Rx postnatal vitamin with probiotics, DHA and chelated iron

Rx Only
Dietary Supplement
30 Softgels

Avion
PHARMACEUTICALS

PRENATE RESTORE

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, dl-, folic acid, pyridoxine hydrochloride, cyanocobalamin, biotin, calcium carbonate, ferrous fumarate, magnesium oxide, lactic acid and doconexent capsule, gelatin coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75854-308
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	85 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]
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	500 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	155 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	45 mg
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	10 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	400 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WHITE WAX (UNII: 7G1J5DA97F)	
CORN OIL (UNII: 8470G57WFM)	
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 (dark blue)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	OmegaRx
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-308-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/17/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/17/2013	

Labeler - Avion Pharmaceuticals, LLC (040348516)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-308)

Revised: 1/2024 Avion Pharmaceuticals, LLC