

**PRIMACARE- calcium ascorbate dihydrate, cholecalciferol, dl-a tocopheryl acetate, riboflavin, niacinamide, folate, biotin, calcium, ferrous asparto glycinate, potassium iodide, magnesium oxide, zinc bisglycinate chelate, alpha linoleic acid, dha, epa pill**  
**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.*

**Rx Only Dietary Supplement**

**DESCRIPTION:** PrimaCare™ is a prescription prenatal/postnatal multivitamin/mineral/essential fatty acid softgel. Each softgel is purple in color and imprinted with “PRIMA” on one side and blank on the other.'

<b>Supplement Facts</b>			
<b>Serving Size: 1 softgel</b>			
<b>Amount per Serving:</b>		<b>% Daily Value</b>	<b>% Daily Value (Pregnant &amp; Lactating Women)</b>
Vitamin C (as calcium ascorbate dihydrate)	25 mg	42%	42%
Vitamin D3 (as cholecalciferol)	1000 IU	250%	250%
Vitamin E (as dl-A tocopheryl acetate)	15 IU	50%	50%
Vitamin B2 (as riboflavin)	1.5 mg	88%	75%
Vitamin B3 (as niacinamide)	10 mg	50%	50%
Vitamin B6 (as pyridoxine HCl)	50 mg	2500%	2000%
Folate (as 1.4 mg Quatrefolic® ((6S)-5, methyltetrahydrofolate acid glucosamine salt molar equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg)	1 mg	250%	125%
Biotin	1 mg	333%	333%
Calcium (as calcium carbonate)	100 mg	10%	8%
Iron (as Sumalate® (ferrous asparto glycinate))	30 mg	167%	167%
Iodine (as potassium iodide)	150 mcg	100%	100%
Magnesium (as magnesium oxide)	50 mg	13%	11%
Zinc (as zinc bisglycinate chelate)	15 mg	100%	100%
Alpha linoleic acid	50 mg	†	†
DHA	300 mg	†	†
EPA	120 mg	†	†

† Daily Value (DV) not established

PrimaCare™ contains flaxseed oil, fish oil and soy.

**OTHER INGREDIENTS:** Gelatin capsule (bovine gelatin, sorbitol, glycerin, purified water, titanium dioxide, FD&C Red #40, caramel coloring, FD&C Blue #1), yellow beeswax and soy lecithin.

**INDICATIONS:** PrimaCare™ 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.

**CONTRAINDICATIONS:** PrimaCare™ 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 (75854-322-30). 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.**

Quatrefolic® is a registered trademark of Gnosis, SpA. Covered by one or more claims of U.S. Patent # 7,947,662 CAS# 1181972-37-1 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.

**MANUFACTURED FOR:**

Avion Pharmaceuticals, LLC  
Alpharetta, Georgia 30022 1-888-61-AVION  
Rev. 1016-06 AV-427

**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.**

**Supplement Facts**  
Serving Size: 1 softgel

Amount per Serving	% Daily Value	% Daily Value
	Based on RDA	Based on RDA
Vitamin C (as calcium ascorbate dihydrate)	25 mg	42%
Vitamin D3 (as cholecalciferol)	1000 IU	200%
Vitamin E (as dl- $\alpha$ -tocopheryl acetate)	15 IU	30%
Vitamin B2 (as riboflavin)	1.5 mg	30%
Vitamin B3 (as niacinamide)	10 mg	20%
Vitamin B9 (as pyridoxine HCl)	50 mg	1000%
Folate (as 1,4 mg Quatrefolic® (5S)-5, methyltetrahydrofolate acid glucosamine salt molar equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg)	1 mg	200%
Biotin	1 mg	333%
Calcium (as calcium carbonate)	100 mg	10%
Iron (as Sumalis® ferrous asparto glycinate)	30 mg	187%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	50 mg	13%
Zinc (as zinc bisglycinate chelate)	15 mg	100%
Alpha linoleic acid	50 mg	1
DHA	200 mg	1
EPA	120 mg	1

**OTHER INGREDIENTS:** Gelatin capsule (bovine gelatin, sorbitol, glycerin, purified water, titanium dioxide, FD&C Red #40, carmine coloring, FD&C Blue #1), yellow beeswax and soy lecithin. (Contains 100 mg of iron and 100 mg of calcium).

**75854-322-30**  
Rx only

**DOSAGE AND ADMINISTRATION:** Before, during and/or after pregnancy, one softgel daily or as directed by a physician.

**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.

**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 30022 1-888-61-AMON  
Rev. 0317-01 AV-390

**ONE PILL WITH 470 MG OMEGA 3 DAILY**

**SUGAR FREE  
LACTOSE FREE  
30 softgels**

**www.primacarerx.com**

**3 75854 32230 2**

**PEEL HERE**

**PRIMACARE**

calcium ascorbate dihydrate, cholecalciferol, dl-a tocopheryl acetate, riboflavin, niacinamide, folate, biotin, calcium, ferrous asparto glycinate, potassium iodide, magnesium oxide, zinc bisglycinate chelate, alpha linoleic acid, dha, epa pill

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75854-322
<b>Route of Administration</b>	oral		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>CALCIUM ASCORBATE</b> (UNII: 183E4W213W) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	25 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	1000 [iU]
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	ALPHA-TOCOPHEROL ACETATE	15 [iU]
<b>riboflavin</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	riboflavin	1.5 mg
<b>niacinamide</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	niacinamide	10 mg
<b>PYRIDOXINE</b> (UNII: KV2JZ1B16Z) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	50 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>Biotin</b> (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	Biotin	1 mg
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CARBONATE	100 mg
<b>potassium iodide</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
<b>magnesium oxide</b> (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	50 mg
<b>ZINC</b> (UNII: J41CSQ7QDS) (ZINC - UNII:J41CSQ7QDS)	ZINC	15 mg
<b>LINOLEIC ACID</b> (UNII: 9KJL21T0QJ) (LINOLEIC ACID - UNII:9KJL21T0QJ)	LINOLEIC ACID	50 mg
<b>OMEGA-3 FATTY ACIDS</b> (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	420 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>FERROUS ASPARTO GLYCINATE</b> (UNII: H7426RGB3L)	30 mg
<b>GELATIN</b> (UNII: 2G86QN327L)	

<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	capsule	<b>Size</b>	24mm
<b>Flavor</b>		<b>Imprint Code</b>	PRIMA
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-322-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/23/2017	

**Labeler** - Avion Pharmaceuticals, LLC (965450542)

**Registrant** - Avion Pharmaceuticals, LLC (965450542)

### Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		965450542	manufacture(75854-322)

Revised: 3/2017

Avion Pharmaceuticals, LLC