

# PrimaCare<sup>®</sup>

## Rx Only Dietary Supplement

**DESCRIPTION:** PrimaCare<sup>®</sup> 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.

### Supplement Facts

Serving Size: 1 softgel

Amount per Serving:		% Daily Value	% Daily Value (Pregnant & Lactating Women)
Vitamin C (as calcium ascorbate dihydrate)	25 mg	40%	40%
Vitamin D3 (as cholecalciferol)	25 mcg	130%	130%
Vitamin E (as dl- $\alpha$ -tocopheryl acetate)	6.75 mg	45%	45%
Vitamin B2 (as riboflavin)	1.5 mg	90%	75%
Vitamin B3 (as niacinamide)	10 mg	50%	50%
Vitamin B6 (as pyridoxine HCl)	50 mcg	2500%	2000%
Folate (as 1.4 mg Quatrefolic <sup>®</sup> (6S)-5,1700 mcg DFE methyltetrahydrofolate acid glucosamine salt (equivalent to 750 mcg of folic acid) and folic acid, USP 250 mcg)	4300 mcg	4300%	2800%
Biotin	1 mg	330%	330%
Calcium (as calcium carbonate)	100 mg	10%	10%
Iron (as Sumalate <sup>®</sup> (ferrous asparto glycinate))	30 mg	170%	170%
Iodine (as potassium iodide)	150 mcg	100%	100%
Magnesium (as magnesium oxide)	50 mg	10%	10%
Zinc (as zinc bisglycinate chelate)	15 mg	100%	100%
Alpha linoleic acid (ALA)	50 mg	†	†
Docosahexaenoic acid (DHA)	300 mg	†	†
Eicosapentaenoic acid (EPA)	120 mg	†	†

† Daily Value (DV) not established

PrimaCare<sup>®</sup> contains flaxseed oil, fish oil and soy.

**OTHER INGREDIENTS:** Beeswax and soy lecithin.

Gelatin capsule (bovine gelatin, caramel coloring, FD&C Blue #1, FD&C Red #40, glycerin, purified water, sorbitol and titanium dioxide).

**INDICATIONS:** PrimaCare<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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:

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**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.**