

PrimaCare[®] ONE

A once-daily prenatal vitamin supplement, including key omega-3 fatty acids (DHA and EPA) and 1 mg folic acid

Rx Only

DESCRIPTION: PrimaCare[®] ONE is a prescription prenatal/postnatal multivitamin/mineral capsule with omega-3 fatty acids. Each purple soft gelatin capsule for oral administration contains:

Essential Fatty Acids:

Omega-3 Fatty Acids	330 mg
Docosahexaenoic Acid (DHA)	260 mg
Eicosapentaenoic Acid (EPA)	40 mg
α -Linolenic Acid (ALA)	30 mg
Linoleic Acid	30 mg

Vitamins:

Vitamin C (as Ester-C ^{®*})	25 mg
Vitamin D ₃ (cholecalciferol)	170 IU
Vitamin E (dl-alpha-tocopheryl acetate)	30 IU
Folic Acid, USP	1 mg
Vitamin B ₆ (pyridoxine hydrochloride)	25 mg

Minerals:

Calcium	150 mg
Iron	
Carbonyl iron (elemental iron)	20 mg
Sumalate ^{™†} (elemental iron)	7 mg

*Ester-C[®] is a patented pharmaceutical grade material consisting of calcium ascorbate and calcium threonate.

Ester-C[®] is a licensed trademark of The Ester C Company.

†Sumalate[™] (ferrous asparto glycinate) is a trademark of Albion International, Inc., Clearfield, Utah. U.S. Patent pending.

Inactive Ingredients: D&C Red No. 33, ethylvanillin, FD&C Blue No. 1, gelatin, glycerine, hydrogenated vegetable oil, lecithin, malic acid, methylparaben, propylparaben, silicon dioxide, soybean oil, succinic acid, titanium dioxide, vegetable shortening, and yellow beeswax.

INDICATIONS: PrimaCare[®] ONE is indicated to provide vitamin/mineral and omega-3 fatty acid supplementation throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. It is also useful for improving nutritional status prior to conception.

CONTRAINDICATIONS: This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNINGS: 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 remain progressive.

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.

PRECAUTIONS

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies on this product have not been performed to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION: Usual dosage is one capsule daily, or as prescribed by a physician.

HOW SUPPLIED: PrimaCare[®] ONE prenatal/postnatal multivitamin/mineral capsules are purple soft gelatin capsules, imprinted "Ther-Rx 200" in white ink, packaged in bottles of 30 capsules (NDC 64011-200-19).

Store at controlled room temperature 15°–30° C (59°–86° F).

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

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Manufactured by Accucaps Industries Limited
Windsor, Ontario, Canada

Marketed by Ther-Rx Corporation
St. Louis, MO 63044

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6,197,329; 6,258,846; 6,569,857; 6,576,666;
6,716,814; 7,112,609.

Other U.S. Patents pending.