

# PreCare Premier™

**A once-daily prenatal supplement with essential vitamins and minerals, including a stool softener and high levels of B vitamins**

## Rx Only

**DESCRIPTION:** PreCarePremier™ is a prescription prenatal multivitamin/mineral nutritional supplement and stool softener. Each dye-free, peach, film-coated caplet for oral administration contains:

### Vitamins:

Vitamin C (as Ester-C**)	.50 mg
Vitamin D <sub>3</sub> (cholecalciferol)	.240 IU
Vitamin E (dl-alpha-tocopheryl acetate)	.3.5 IU
Vitamin B <sub>1</sub> (thiamine mononitrate, USP)	.3 mg
Vitamin B <sub>2</sub> (riboflavin, USP)	.3.4 mg
Vitamin B <sub>3</sub> (niacinamide)	.20 mg
Vitamin B <sub>6</sub> (pyridoxine hydrochloride, USP)	.50 mg
Folic Acid, USP	.1 mg
Vitamin B <sub>12</sub> (cyanocobalamin)	.12 mcg

### Minerals:

Calcium (calcium carbonate)	.250 mg
Iron (elemental iron as Sumalate™)	.30 mg
Magnesium (magnesium oxide, USP)	.25 mg
Zinc (zinc oxide, USP)	.15 mg
Copper (cupric oxide)	.2 mg

### Other:

Docusate Sodium	.50 mg
Succinic Acid	.35 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:** acacia, butylated hydroxy anisole, butylated hydroxy toluene, carnauba wax, citric acid, croscarmellose sodium, gelatin, hypromellose, lactose monohydrate, magnesium stearate, malic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, red iron oxide, silicon dioxide, sodium benzoate, sodium citrate, sodium lauryl sulfate, sorbic acid, starch, sucrose, titanium dioxide, triacetin, vegetable oil, and yellow iron oxide.

**INDICATIONS:** PreCare Premier™ is indicated to provide vitamin and mineral supplementation and help reduce constipation throughout pregnancy and during the postnatal period – for both lactating and non-lactating mothers. 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 B<sub>12</sub> 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 the 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 caplet daily, or as prescribed by a physician.

**HOW SUPPLIED:** PreCare Premier™ multivitamin/mineral caplets are dye-free, peach, film-coated caplets, debossed "Ther-Rx" on one side and "195" with a partial bisect on the other side, packaged in bottles of 30 caplets (NDC 64011-195-19).

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

U.S. Patent Nos.: 4,822,816; 5,070,085; 5,494,681;  
5,516,925; 6,197,329; 6,228,388; 6,569,857;  
6,716,814. Other U.S. Patents pending.

**References:** 1. IMS Health Market date, December 2006-September 2007. 2. PreCare Premier™ prescribing information, Ther-Rx Corporation, April 2007. 3. Docusate, Jackson Siegelbaum Gastroenterology Web site. Available at: <http://www.picare.com/pated/docusate.htm>. Accessed May 29, 2007. 4. Wald NJ. Folic acid and the prevention of neural-tube defects. *N Engl J Med.* 2004;350:101-103. 5. Sahakian V, Rouse D, Sipes S, Rose N, Niebyl J. Vitamin B6 is effective therapy for nausea and vomiting of pregnancy: a randomized, double-blind placebo-controlled study. *Obstet Gynecol.* 1991;78:33-36. 6. Centers for Disease Control and Prevention (CDC). Recommendations to prevent and control iron deficiency in the United States. *MMWR Recomm Rep.* 1998;47:1-29. 7. Dietary supplement fact sheet: Calcium. NIH Office of Dietary Supplements. National Institutes of Health Web site. Available at: <http://ods.od.nih.gov/factsheets/Calcium.asp>. Accessed March 5, 2007.