

PreCare Premier™ delivers 1 mg folic acid
plus a bundle of additional benefits¹



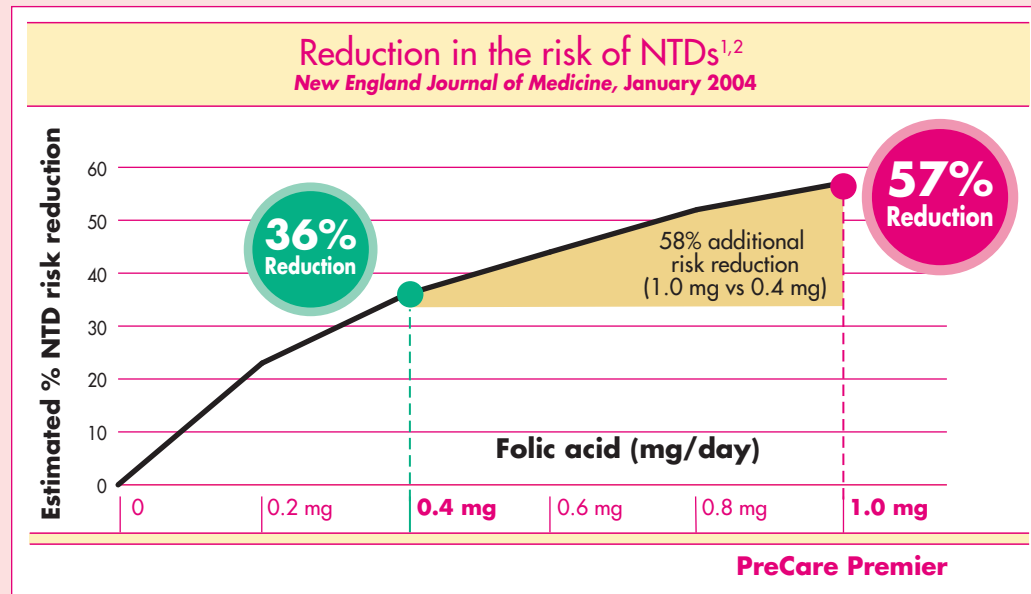
PreCare
Premier™

ther-Rx Prenatal
Vitamins

Right for each mom and baby

1 mg folic acid provides additional risk reduction against neural tube defects (NTDs)

- The 1 mg folic acid in PreCare Premier™ is estimated to provide an **additional 58% risk reduction** against NTDs compared to 0.4 mg folic acid^{1,2}
 - Only folic acid has been clinically proven to reduce NTDs—and the effect is **dose related**^{2,3}



Dose-related benefits of folic acid also apply to women with folic acid enzyme mutation

- Women with a folic acid enzyme mutation metabolize folic acid, although at a slower rate, and may require **higher doses of folic acid**, like the 1 mg in PreCare Premier^{1,4,5}

PreCare Premier contains folic acid, the *only* source of folate proven to reduce NTDs^{1,3}

“Ethical constraints would not readily allow for a clinical trial to prove the effectiveness of 5-MTHF [Metafolin®] in the prevention of NTDs due to the accepted risk reduction recognized with FA [folic acid].”

—McGregor JA. *OBG Management*. 2005;(suppl):S6.⁴

- PreCare Premier contains folic acid, which is endorsed by the following⁶⁻¹⁰:
 - American College of Obstetricians and Gynecologists
 - Centers for Disease Control and Prevention
 - March of Dimes®
 - Institute of Medicine
 - American Academy of Pediatrics
 - National Council on Folic Acid
- None of these organizations have recommended the use of Metafolin⁶⁻¹⁰

PreCare Premier offers folic acid plus additional benefits

- PreCare Premier is a small, once-daily prenatal vitamin with docusate sodium¹
- PreCare Premier contains a high level of vitamin B₆ to help relieve symptoms of morning sickness^{1,11}
- PreCare Premier also provides patients with the CDC-recommended amount of 30 mg iron^{1,12}

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.

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.



Metafolin® is a registered trademark of Merck KGaA, Germany.

March of Dimes® is a registered trademark of March of Dimes.

PreCare
Premier™

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: PreCare Premier™ 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 ₃ (cholecalciferol)	.240 IU
Vitamin E (dl-alpha-tocopheryl acetate)	3.5 IU
Vitamin B ₁ (thiamine mononitrate, USP)	.3 mg
Vitamin B ₂ (riboflavin, USP)	3.4 mg
Vitamin B ₃ (niacinamide)	.20 mg
Vitamin B ₆ (pyridoxine hydrochloride, USP)	.50 mg
Folic Acid, USP	.1 mg
Vitamin B ₁₂ (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 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 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

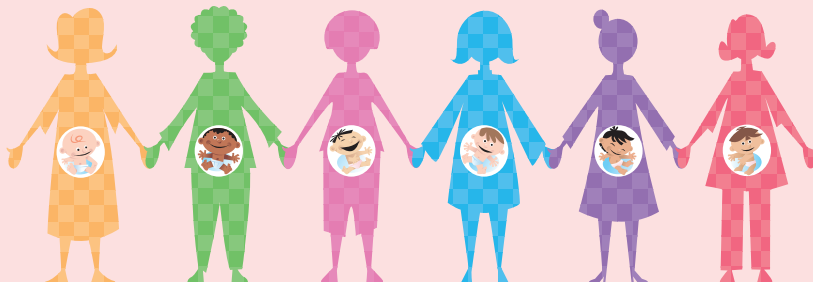
U.S. Patent Nos.: 4,822,816; 5,070,085; 5,494,681; 5,516,925; 6,197,329; 6,228,388; 6,569,857; 6,716,814. Other U.S. Patents pending.

References: 1. PreCare Premier™ prescribing information, Ther-Rx Corporation, April 2007. 2. Wald NJ. Folic acid and the prevention of neural-tube defects. *N Engl J Med.* 2004;350:101-103. 3. Pentieva K, McNulty H, Reichert R, et al. The short-term bioavailabilities of [6S]-5-methyltetrahydrofolate and folic acid are equivalent in men. *J Nutr.* 2004;134:580-585. 4. McGregor JA. Folic acid: are recommended levels always adequate? *OBG Manage.* 2005;(suppl):S1-S8. 5. Botto LD, Qian Y. 5, 10-methylenetetrahydrofolate reductase gene variants and congenital anomalies: a HuGe review. *Am J Epidemiol.* 2000;151:862-877. 6. American College of Obstetricians and Gynecologists. Healthy women: national folic acid awareness week. Available at: http://www.acog.org/acog_districts/dist_notice.cfm?reno=1&bulletin=1864. Accessed August 13, 2007. 7. March of Dimes Pregnancy & Newborn Health Education Center. Folic acid. Available at: http://www.marchofdimes.com/printableArticles/173_769.asp. Accessed August 13, 2007. 8. Centers for Disease Control and Prevention. Folic acid: why folic acid is so important. Available at: <http://www.cdc.gov/ncbddd/folicacid/overview.htm>. Accessed August 13, 2007. 9. Committee on Genetics. American Academy of Pediatrics. Folic acid for the prevention of neural tube defects. *Pediatrics.* 1999;104:325-327. 10. National Council on Folic Acid. Folic acid: you don't know what you're missing! Available at: <http://www.folicacidinfo.org/campaign/docs/FolicAcidBroEng.pdf>. Accessed August 13, 2007. 11. Sahakian V, Rouse D, Sipes S, Rose N, Niebly 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. 12. 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.



For more information on PreCare Premier™, call us at 877-567-7676 or visit www.precarepremier.com or www.ther-rx.com.

For more information, please see accompanying full prescribing information.



PreCare Premier™

Ther-Rx Corporation is a proud supporter of March of Dimes

‡March of Dimes does not endorse specific products or brands.

Ther-Rx Prenatal Vitamins

Right for each mom and baby