

- PreQue® 10

Nutrition During Pregnancy

PreQue® 10 Nutritional Ingredients

Oxidative Stress During Pregnancy

Coenzyme Q10

Lycopene

DHA Supplementation with *life'sDHA*™

Flexible Dosing

Motherhood and You

• Patient Education Brochure

• Due Date Calculator

Helpful Links



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.

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.

See package insert for complete prescribing information.

Full Prescribing Information

DESCRIPTION

PreQue® 10 is a patent-pending product, available by prescription only. **PreQue® 10** is designed specifically to meet the extra nutritional demands of a pregnant woman to satisfy the needs of her growing fetus and to help improve the health status of both the mother and her infant. **PreQue® 10** is formulated to reduce oxidative stress, the imbalance between oxygen free radicals and essential antioxidants, helping to maintain homeostasis and strengthen vascular endothelial lining cells.

Each slender, oblong, and coated **PreQue® 10** tablet is light violet in color and imprinted with "PreQue" on one side and "10" on the opposite side. **PreQue® 10** is the only prenatal product to incorporate more than 25 mg DHA into the tablet.

PreQue® 10 contains the following micronutrients, balancing tablet size with essential ingredients:

	Per tablet	Per Daily Dose
Vitamin A (beta-carotene)	1,250 IU	2500 IU
Vitamin C (Pharm-C®)	30 mg	60 mg
Vitamin B ₁ (thiamine mononitrate)	1 mg	2 mg
Vitamin B ₂ (riboflavin)	1.7 mg	3.4 mg
Vitamin B ₁₂ (cyanocobalamin)	1 mcg	2 mcg
Vitamin D ₃ (cholecalciferol)	120 IU	240 IU
Vitamin E (d-alpha-tocopheryl succinate)	15 IU	30 IU
Elemental Iron (as carbonyl iron)	15 mg	30 mg
Copper (as cupric oxide)	1 mg	2 mg
Magnesium (as magnesium oxide)	10 mg	20 mg
Selenium (as sodium selenate)	7.5 mcg	15 mcg
Zinc (as zinc oxide)	12.5	25 mg
CoQ10 (co-enzyme Q-10)	50 mg	100 mg
Lycopene	5 mg	10 mg

	Per tablet	Per Daily Dose
Folic Acid	0.5 mg	1 mg
<i>life'sDHA</i> ™ (docosahexaenoic acid)	50 mg	100 mg

*Pharm-C® is a proprietary blend of ascorbic acid, calcium ascorbate and sodium ascorbate. Pharm-C® is a registered trademark of Nexgen Pharma, Inc.
†*life'sDHA*™ is a trademark of Martek Biosciences Corporation.

Before, during, and/or after pregnancy, **two (2) PreQue® 10 tablets should be taken daily** or as directed by a physician. The total daily dose of **PreQue® 10** may be taken at one time or in divided doses.

PreQue® 10 is designed specifically to meet the extra nutritional demands of a pregnant woman to satisfy the needs of her growing fetus, help improve the health status of both the mother and her infant, and to reduce oxidative stress. Pregnancy is associated with an increased susceptibility to oxidative stress.¹ CoQ10 is an essential component of oxidative phosphorylation at the mitochondrial level, and also functions to stabilize cell membranes, as well as acting as a potent antioxidant, which has been postulated to be a modulator of gene expression and free radical-induced cell damage.^{2,3} Data from both clinical and preclinical studies indicate that CoQ10 is safe for use as a dietary supplement, does not interfere with the biosynthesis of endogenous CoQ9/CoQ10, nor does it accumulate into plasma or tissues.⁴ Oxidative stress, and CoQ10 deficiency, has been associated with preeclampsia, a serious medical complication that may occur during pregnancy.^{3,5-7} **PreQue® 10** also contains lycopene. Lycopene is a carotenoid present in human serum and skin as well as the liver, adrenal glands, lungs, prostate, and colon. This micronutrient is believed to possess antioxidant and antiproliferative properties.^{8,9} Lycopene deficiency has been associated with preeclampsia and fetal growth restriction.¹⁰ In addition to CoQ10 and lycopene, **PreQue® 10** has other ingredients with antioxidant properties, such as vitamin A, vitamin C, vitamin E and selenium. The antioxidants in **PreQue® 10** help to maintain vascular health. The other micronutrients in **PreQue® 10** provide balanced prenatal nutrition supplementation to help ensure optimal infant and maternal outcomes.

Other Ingredients: Microcrystalline cellulose, mannitol, algal oil, glucose syrup solids, high oleic sunflower oil, sodium caseinate, soy protein, tomato, croscarmellose sodium, docusate sodium, silicon dioxide, ethylcellulose, stearic acid, polyvinyl alcohol, alginate, arabic gum, pea starch, tricalcium phosphate, polyethylene glycol, ascorbyl palmitate, mixed natural tocopherols, povidone, soy lecithin, tetrasodium diphosphate, FD&C red no. 40, talc, food starch, gelatin, sucrose, tocopherol, magnesium stearate, sodium benzoate, titanium dioxide, hypromellose, dicalcium phosphate, FD&C blue no. 2, corn syrup, natural flavors.

PreQue® 10 does not contain ethanol, caffeine, iodine or gluten.
Allergen Information: Contains milk and soy.

Prenatal Nutrition:

Suboptimal prenatal diets have been associated with serious maternal medical complications and developmental delays after birth, as well as birth defects and downstream chronic health issues for the newborn.¹¹ While the risk of complications is higher among women whose diets are deficient in micronutrients, even a healthy, carefully planned diet may not be sufficient to meet the increased demands of pregnancy.¹¹ The ability of many pregnant women to consistently consume an optimal diet throughout pregnancy is also limited by factors such as fatigue, nausea, food cravings, and busy lifestyles.¹¹ In an attempt to mitigate the complications associated with poor diets, the American Dietetic Association has recommended that pregnant women have appropriate weight gain, that they consume a variety of foods in accordance with the Food Guide Pyramid during pregnancy, have appropriate and timely vitamin and mineral supplementation added to the diet and that alcohol, tobacco, and other harmful substances be avoided.¹² In addition, many

experts recommend prenatal nutritional supplements to ensure optimal infant and maternal outcomes.¹¹

Bz Pregnancy is also associated with an increased susceptibility to oxidative stress. Oxidative stress results from the imbalance between oxygen free radicals and the essential antioxidants that maintain homeostasis in the vascular endothelium.¹ An excess of oxygen free radicals can cause adverse outcomes for the mother, the developing fetus, and the child after birth.¹ The increased physiologic demands of pregnancy are associated with increased basal oxygen consumption, changes in energy substrate used by different organs, and production of free radicals that damage the maternal vascular endothelial lining cells.¹ Transitional metals, especially cadmium, which are abundant in the placenta where extensive vasculature is present, are also involved in the production of free radicals.¹ Pregnancy complications such as preeclampsia and preterm labor can result from oxygen free radical damage.¹ In addition, pregnancy complications also increase oxidative stress. Several studies have demonstrated that serum levels of CoQ10 in preeclamptic women were significantly less than those in nonpreeclamptic women.^{3,5,6}

INDICATIONS:

PreQue® 10 is a patent-pending product, available by prescription only, designed specifically to meet the extra nutritional demands of a pregnant woman to satisfy the needs of her growing fetus and to help improve the health status of both the mother and her infant. **PreQue® 10** is formulated to reduce oxidative stress, the imbalance between oxygen free radicals and essential antioxidants, helping to maintain homeostasis and strengthen vascular endothelial lining cells. **PreQue® 10** replenishes CoQ10, helping to restore CoQ10 (co-enzyme Q-10) levels.

CONTRAINDICATIONS: **PreQue® 10** 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.

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: Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body has been associated with cyanocobalamin.

DOSAGE AND ADMINISTRATION: Before, during, and/or after pregnancy, **two (2) PreQue® 10 tablets should be taken daily** or as directed by a physician. The total daily dose of **PreQue® 10** may be taken at one time or in divided doses.

HOW SUPPLIED Bottles of 60 tablets for commercial sale (NDC 59702-710-60) with a child resistant closure and in sample cartons of 6 tablets in child resistant blisters (NDC 59702-710-36) for patient trial available only through physician offices.

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

DISPENSE IN A TIGHT, LIGHT RESISTANT CONTAINER AS DEFINED BY THE USP/NF WITH A CHILD RESISTANT CLOSURE.
Store at 20 to 25°C (68 to 77°F).

NOTICE: Contact with moisture can discolor or erode the tablet.

U.S. Patents Pending

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