PreQue 10™
Rx Prenatal Nutrition
with CoQ10 and Lycopene

Revised: September 2014
Rx only
7124-0014-99-OS

DESCRIPTION:

PreQue 10 is available by prescription only and is designed specifically to meet the extra nutritional demands of a woman before, during, and/or after pregnancy. 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.

Each PreQue 10 tablet and daily dose of two (2) tablets contains the following ingredients:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount per tablet</th>
<th>Amount per daily dose (2 tablets)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (beta-carotene)</td>
<td>1,250 IU</td>
<td>2,500 IU</td>
</tr>
<tr>
<td>Vitamin C (Pharm-C®*)</td>
<td>30 mg</td>
<td>60 mg</td>
</tr>
<tr>
<td>Vitamin B1 (thiamine mononitrate)</td>
<td>1 mg</td>
<td>2 mg</td>
</tr>
<tr>
<td>Vitamin B2 (riboflavin)</td>
<td>1.7 mg</td>
<td>3.4 mg</td>
</tr>
<tr>
<td>Vitamin B12 (cyanocobalamin)</td>
<td>1 mcg</td>
<td>2 mcg</td>
</tr>
<tr>
<td>Vitamin D3 (cholecalciferol)</td>
<td>120 IU</td>
<td>240 IU</td>
</tr>
<tr>
<td>Vitamin E (d-alpha-tocopheryl succinate)</td>
<td>15 IU</td>
<td>30 IU</td>
</tr>
<tr>
<td>Docusate Sodium</td>
<td>25 mg</td>
<td>50 mg</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>0.5 mg</td>
<td>1 mg</td>
</tr>
<tr>
<td>Elemental Iron (as carbonyl iron)</td>
<td>15 mg</td>
<td>30 mg</td>
</tr>
<tr>
<td>Copper (as cupric oxide)</td>
<td>1 mg</td>
<td>2 mg</td>
</tr>
<tr>
<td>Magnesium (as magnesium oxide)</td>
<td>10 mg</td>
<td>20 mg</td>
</tr>
<tr>
<td>Selenium (as sodium selenate)</td>
<td>7.5 mcg</td>
<td>15 mcg</td>
</tr>
<tr>
<td>Zinc (as zinc oxide)</td>
<td>12.5 mg</td>
<td>25 mg</td>
</tr>
<tr>
<td>CoQ10 (co-enzyme Q-10)</td>
<td>50 mg</td>
<td>100 mg</td>
</tr>
<tr>
<td>Lycopene</td>
<td>5 mg</td>
<td>10 mg</td>
</tr>
<tr>
<td>life’sDHA™ ** (docosahexaenoic acid)</td>
<td>50 mg</td>
<td>100 mg</td>
</tr>
</tbody>
</table>

*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’s DHA™ is a trademark of Martek Biosciences Corporation.

Other Ingredients: Algal oil, microcrystalline cellulose, glucose syrup solids, mannitol, pea starch, alginate, natural flavors, croscarmellose sodium, silicon dioxide, high oleic sunflower oil, sodium caseinate (milk), soy protein, ethylcellulose, stearic acid, polyvinyl alcohol, tricalcium phosphate, ascorbyl palmitate, mixed natural tocopherols, soy lecithin, tetradsodium diphosphate, povidone, arabic gum, titanium dioxide, polyethylene glycol, talc, hypromellose, magnesium stearate, sodium benzoate, tomato lipids, gelatin, sucrose, food starch, modified food starch, FD&C Blue #2 Indigo Carmine Aluminum Lake, FD&C Red #40 Allura Red AC Aluminum Lake, tocopherol concentrate, dicalcium phosphate, medium chain triglycerides.

Allergen Information: Contains milk and soy.
PreQue 10 is designed specifically to meet the extra nutritional demands of a pregnant woman. PreQue 10 contains lycopene. Lycopene is a carotenoid present in human serum and skin as well as the liver, adrenal glands, lungs, prostate, and colon. In addition to CoQ10 and lycopene, PreQue 10 has other ingredients with antioxidant properties, such as vitamin A, vitamin C, vitamin E and selenium.

Prenatal Nutrition:
Good maternal nutrition is a key factor influencing the health of the mother and child. (1)

The American Dietetic Association recommends that pregnant women have appropriate weight gain, consumption of a variety of foods in accordance with the Dietary Guidelines for Americans, have appropriate and timely vitamin and mineral supplementation, and that alcohol, tobacco, and other harmful substances be avoided. (2)

INDICATIONS:

PreQue 10 is designed specifically to meet the extra nutritional demands of a woman before, during, and/or after pregnancy.

CONTRAINDICATIONS:

PreQue 10 is contraindicated in patients with a known hypersensitivity to any of the ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

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.

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 1mg 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.

CAUTION:

Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

DOSAGE AND ADMINISTRATION:

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

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

Bottles of 60 tablets for commercial sale (NDC 52544-079-60) with a child-resistant closure.

KEEP 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). [See USP controlled room temperature.]

References:


To report a serious adverse event or obtain product information, call Actavis Medical Communications 1-800-272-5525.

PreQue 10 is a trademark licensed exclusively to Watson Pharma, Inc. U.S. Patent No. 7,964,189

life’s DHA™ is a trademark of Martek Biosciences Corporation.

Distributed By:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

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