IN-607201-01
Rev. 10/2013

natelle® ONE

Rx Prenatal Vitamin & Plant-Based DHA.
Now with 28 mg Iron

K MED.

Description: Natelle® One capsules for oral administration are supplied as oblong red soft gelatin capsules, imprinted with "Natelle1" in white ink.

Each capsule contains:

Docosahexaenoic Acid (DHA) from Algal Oil	250 mg
Eicosapentaenoic Acid (EPA)	Not more than 0.625 mg
Calcium (Tricalcium Phosphate)	102 mg
Iron (Ferrous Fumarate)	28 mg
Vitamin C (Ascorbic Acid)	30 mg
Vitamin B-6 (Pyridoxine HCl)	25 mg
Vitamin E (D-Alpha Tocopherol)	30 IU
Folic Acid	1 mg

DHA is an **omega-3 fatty acid**. The DHA in Natelle® One is derived from Algal Oil (C.cohnii). 625 mg of Algal Oil is equivalent to 250 mg of DHA.

Inactive Ingredients: Gelatin (Bovine), Beeswax, Glycerine, Soybean Oil, Lecithin, Titanium Dioxide, Ethyl Vanillin.

Indications and Usage: Natelle® One is indicated to provide vitamin/mineral and DHA omega-3 fatty acid supplementation to women throughout pregnancy, during the postnatal period for both lactating and non–lactating mothers, and throughout the childbearing years. Natelle® One may be beneficial in improving the nutritional status of women prior to conception.

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

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Warnings: Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

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.

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.

To report SUSPECTED ADVERSE REACTIONS, contact Meda Pharmaceuticals Inc. at 1-877-999-8405 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Dosage and Administration: One capsule daily, or as directed by a physician.

How Supplied: Supplied in child resistant bottles of 30 capsules (NDC 0037-6072-30).

Store at controlled room temperature 20°–25°C (68°–77°F); excursions permitted to 15°–30°C (59°–86°F).

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

Rx Only

Distributed by:

MEDA PHARMACEUTICALS™
Somerset, New Jersey 08873-4120

life's DHA™
HEALTHY BRAIN, EYES, HEART