

# Prenaisance Plus

## Rx Only

**DESCRIPTION:** Prenaisance Plus is a prescription prenatal/postnatal dietary supplement in softgel form, which contains multivitamins and minerals along with DHA. Each softgel is purple in color and imprinted with "343" on one side.

### SUPPLEMENT FACTS

#### Serving Size 1 Softgel

Each Softgel Contains	Amount	% Daily Value
Calcium (citrate tetrahydrate)	100 mg	10%
Iron (Carbonyl Iron)	28 mg	160%
Vitamin D3 (cholecalciferol)	10 mcg	50%
Vitamin E (dl-alpha tocopherol acetate)	13.5 mg	90%
Vitamin B6 (pyridoxine HCl)	25 mg	1250%
Folic Acid (1000 mcg folic acid, USP)	1700 mcg DFE	480%
DHA (docosahexaenoic acid)	250 mg	†
Docusate Sodium	50 mg	†

† Daily value (DV) not established.

**OTHER INGREDIENTS:** Beeswax, orange cream flavor, soy lecithin and soybean oil. Shell ingredients: Bovine gelatin, carmine, ethyl vanillin, FD&C Blue #1, FD&C Red #40, glycerin, purified water and titanium dioxide. **Contains soy.**

**INDICATIONS:** Prenaisance Plus is a multivitamin/mineral prescription dietary supplement indicated for use in improving the nutritional status of women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and nonlactating mothers.

**CONTRAINDICATIONS:** This product 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 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 progress.

**ADVERSE REACTIONS:** Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

**CAUTION:** Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 g (1000 mg) daily.

**DOSAGE AND ADMINISTRATION:** Usual adult dose is one (1) softgel daily or as directed by a physician.

**KEEP OUT OF REACH OF CHILDREN.**

**HOW SUPPLIED:** Prenaisance Plus is supplied in child-resistant bottles of 30 softgels (42192-343-30). The listed product number is not a National Drug Code, but has merely been formatted to comply with standard industry practice for pharmacy and insurance computer systems.

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F). [See USP, "Controlled Room Temperature"]. Protect from light and heat.

**KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.**

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please note: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the dietary ingredients, other ingredients and information provided herein.

**THESE STATEMENTS HAVE NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE.**

#### MANUFACTURED FOR:

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