

Prenaisance Rx Only

DESCRIPTION: Prenaisance is a prescription prenatal/postnatal dietary supplement in softgel form, which contains multivitamins and minerals along with DHA. Each softgel is dark purple in color and imprinted with "341" on one side.

SUPPLEMENT FACTS

Serving Size 1 Softgel

Each Softgel Contains	Amount	% Daily Value
Vitamin C (ascorbic acid)	28 mg	47%
Calcium (tribasic calcium phosphate)	160 mg	16%
Iron (ferrous fumarate)	29 mg	161%
Vitamin D3 (cholecalciferol)	800 IU	200%
Vitamin E (d-alpha tocopherol)	30 IU	100%
Vitamin B6 (pyridoxine HCl)	25 mg	1250%
Folic Acid	1.25 mg	313%
DHA (docosahexaenoic acid)	325 mg	†
Docosate Sodium	55 mg	†

† Daily value (DV) not established.

OTHER INGREDIENTS: Bovine gelatin, glycerin, soybean oil, soy lecithin, purified water, yellow beeswax, orange cream flavor, FD&C Red #40, titanium dioxide and FD&C Blue #1.

INDICATIONS: Prenaisance 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 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 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 is supplied in child-resistant bottles of 30 softgels (42192-341-30). 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:

Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802
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