



Se-Tan Soft Gel DHA Capsules

Rx Only

Se-Tan DHA

Ferrous Fumarate/
Polysaccharide Iron
Complex Vitamin Mineral
Complex Prenatal Soft Gel
Capsules With DHA

Rx Only

DESCRIPTION: Each dark blue liquid filled soft gel capsule contains:

Ferrous Fumarate

(Elemental Iron) . . . 15 mg

Polysaccharide Iron Complex

(Elemental Iron) . . 15 mg
(Equivalent to about 30 mg of elemental iron)

Vitamin C

(Sodium Ascorbate) . . 20 mg

Folic Acid 1 mg

Vitamin B6

(Pyridoxine HCl) . . . 25 mg

Omega-3 Fatty Acids

. 310.1 mg
(Derived from at least 450 mg Fish Oil)

Docosahexaenoic Acid (DHA) 215.12 mg

Eicosapentaenoic Acid (EPA) 53.46 mg

Inactive Ingredients: Bovine Gelatin, Ethyl Vanillin, FD&C Blue, FD&C Yellow #3, Glycerin, Natural Creamy Orange Flavor, Purified Water, Sodium Citrate, Soy Lecithin, Soybean Oil, Titanium Dioxide, Vitamin E, Yellow Bees Wax.

INDICATIONS: Se-Tan DHA is a prescription prenatal vitamin-mineral preparation containing omega-3 fatty acid supplements designed to supply nutritional supplementation for women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Se-Tan DHA may also be used to improve the nutritional status of women before conception.

CONTRAINDICATIONS:

Se-Tan DHA is contraindicated in patients with known hypersensitivity to any of its ingredients, including fish or fish oil; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

WARNING: Accidental overdose of iron-containing products is the leading cause of fatal poisoning in children under six. Keep this and all drugs 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 from fish oils per day may have potential antithrombotic effects, including an increased bleeding time and INR (international normalized ratio). DHA should be avoided in patients with inherited or acquired bleeding diatheses, including those taking anticoagulants.

Folic acid alone is improper therapy in the treatment for pernicious anemia and other megaloblastic anemias where Vitamin B₁₂ is deficient.

PRECAUTIONS:

General: Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

Pediatric Use: Safety and effectiveness of this product have not been established in pediatric patients.

Geriatric Use: No clinical studies have been performed in patients age 65 and over to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function and or concomitant diseases.

Adverse Reactions:

Folic Acid:

Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.

Ferrous Fumarate:

Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving Se-Tan DHA after meals may control occasional G.I. disturbances. Se-Tan DHA is best absorbed when taken at bedtime.

OVERDOSE: Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300-mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Se-Tan DHA should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this and all other drugs out of the reach of children.

Treatment: For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

DOSAGE AND ADMINISTRATION:

Adults (persons over 12 years of age), one (1) soft gel capsule daily, orally, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12.

HOW SUPPLIED: Se-Tan DHA are dark blue, oblong, liquid filled soft gel capsules imprinted "T513". Child resistant bottles of 90 soft gel capsules. **NDC 13925-119-90.** Dispense in a tight, light resistant container as defined in the USP/NF with a child resistant closure.



Storage: Store at controlled room temperature 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Keep in a cool dry place.

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN

Rx Only.

RESERVED FOR PROFESSIONAL RECOMMENDATION.

Manufactured for:
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