

Taron™-C DHA Prescribing Information

Supplement Facts

Serving Size: 1 Softgel Capsule
Servings Per Container: 30

	Amount Per Serving	% DV for Pregnant and Lactating Women
Calories	5.0	†
Vitamin C* (Ascorbic Acid)	25 mg	21%
Thiamin (as Thiamin Mononitrate)	2 mg	143%
Riboflavin	3 mg	188%
Niacin (as Niacinamide Ascorbate)	1.8 mg NE	10%
Vitamin B₆ (as Pyridoxine HCl)	25 mg	1250%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	278%
Vitamin B₁₂ (Cyanocobalamin)	12.5 mcg	446%
Biotin	300 mcg	857%
Pantothenic Acid (as d-Calcium Pantothenate)	5 mg	71%
Iron (as Ferrous Fumarate and Polysaccharide Iron Complex)	35 mg	130%
Magnesium (as Magnesium Sulfate)	5 mg	1%
Zinc (as Zinc Sulfate)	10 mg	77%
Copper (as Cupric Sulfate)	2 mg	154%
Omega-3 Fatty Acids	200 mg	†
DHA (Docosahexaenoic Acid)	156 mg	†
EPA (Eicosapentaenoic Acid)	39 mg	†

† Daily Value (DV) not established.

* Also containing Ascorbic Acid Precursors as (1) Acid Metabolites including niacinamide ascorbate, calcium ascorbate, magnesium ascorbate, potassium ascorbate and sodium ascorbate (2) Basic Amino Acids including lysine acetate; (3) Flavonoids including hesperidin; and (4) Glutathione

Other Ingredients: Bovine Gelatin, Glycerin, Yellow Beeswax, Soy Lecithin, Purified Water, Orange Cream Flavor O.S, Sorbitol, Titanium Dioxide, Ethyl Vanillin, FD&C Blue #1.

THIS PRODUCT CONTAINS SOY AND FISH (TUNA, MAY INCLUDE ANCHOVY AND/OR SARDINE).

Taron™-C DHA is a prescription multivitamin/mineral indicated to provide omega-3 fatty acid supplementation throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. Taron™-C DHA may be useful in improving the nutritional status of women prior to conception.

CONTRAINDICATIONS

Taron™-C DHA is contraindicated in patients with a known hypersensitivity to any of the ingredients including soy or fish products. All iron compounds are contraindicated in patients with hemochromatosis, hemosiderosis, or hemolytic anemias.

WARNINGS

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 an improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

Pediatric Use: Safety and effectiveness in pediatric populations have not been established.

Geriatric Use: Safety and effectiveness in elderly populations have not been established.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic tests (e.g. troponin) and hormone tests, and may lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

DRUG INTERACTIONS

There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin, Clopidogrel).

ADVERSE REACTIONS

Folic Acid: Allergic sensitization has 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 Taron™-C DHA after meals may control occasional G.I. disturbances. Taron™-C DHA is best absorbed when taken at bedtime.

OVERDOSAGE

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. Taron™-C DHA should be stored beyond the reach of children to prevent against accidental iron poisoning.

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.

DESCRIPTION

Taron™-C DHA is a blue, oval softgel capsule containing a dark brown oil, imprinted with "T536".

DIRECTIONS FOR USE

Adults (over 12 years of age) may take one capsule daily 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

Taron™-C DHA is dispensed in child-resistant bottles of 30 softgel capsules.
Product Code: 13811-536-30

STORAGE: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature].

KEEP OUT OF REACH OF CHILDREN.

For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call Trigen Laboratories, LLC at 1-888-9-TRIGEN (1-888-987-4436) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Customer Service: 1-888-987-4436

Manufactured for:
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