

TRISTART DHA- ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacin, pyridoxine hydrochloride, levomefolate magnesium, folic acid, cyanocobalamin, iron pentacarbonyl, potassium iodide, magnesium oxide, doconexent, and icosapent capsule, liquid filled

CarWin Pharmaceutical Associates, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

**TriStart DHA
PRENATAL SUPPLEMENT**

| Supplement Facts | | | |
|---|---------------------------|----------------------|---|
| Serving Size: 1 Softgel | | | |
| Servings per container: 30 | | | |
| | Amount Per Serving | % Daily Value | % Daily Value for Pregnant and Lactating Women |
| Vitamin C (as ascorbic acid) | 55 mg | 92% | 92% |
| Vitamin D3 (as cholecalciferol) | 1000 IU | 250% | 250% |
| Vitamin E (as d-alpha-tocopheryl acetate) | 15 IU | 50% | 50% |
| Thiamin (as thiamine HCl, Vitamin B1) | 1.3 mg | 87% | 76% |
| Riboflavin (Vitamin B2) | 1.8 mg | 106% | 90% |
| Niacin (as nicotinic acid) | 5 mg | 25% | 25% |
| Vitamin B6 (as pyridoxine HCl) | 35 mg | 1750% | 1400% |
| Folate (as 630 mcg of L-Methylfolate Magnesium, molar equivalent to 600mcg of L-Methylfolic acid; and 400mcg of folic acid) | 1 mg | 250% | 125% |
| Vitamin B12 (as cyanocobalamin) | 14 mcg | 233% | 175% |
| Iron (as carbonyl iron) | 31 mg | 172% | 172% |
| Iodine (as Potassium Iodide) | 200 mcg | 133% | 133% |
| Magnesium (as Magnesium Oxide) | 30 mg | 8% | 7% |
| Docosahexaenoic Acid (DHA) | 200mg | * | * |
| Eicosapentaenoate Acid (EPA) | 15 mg | * | * |

* Daily Values (DV) not established.

OTHER INGREDIENTS: Gelatin (bovine), Glycerin, Purified Water, Yellow Bees Wax, Caramel Powder, Soy Lecithin, Natural Orange Flavor, Ethyl Vanillin.

Contains: Soy and Fish

TriStart DHA™ Softgel capsules are dye free, lactose, gluten and sugar free. They do not contain any artificial flavors or sweeteners. TriStart DHA™ contains bovine gelatin.

INDICATIONS

TriStart DHA™ is an orally administered multivitamin/multimineral fatty acid dietary supplement indicated to improve the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. TriStart DHA™ can also be beneficial in improving the nutritional status of women prior to conception.¹

¹ This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.

CONTRAINDICATIONS

TriStart DHA™ 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. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Caution is recommended in patients taking anticonvulsant medications as folate may interfere with anticonvulsant medication, and may lower seizure threshold. Furthermore, anticonvulsant medications may interfere with folate metabolism.

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 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA and EPA) 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.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact CarWin Pharmaceutical Associates, LLC at 1-985-288-5122

DIRECTIONS

Adults

Take one softgel daily with or without food, or as prescribed by a healthcare practitioner.

Children under 12

Consult a doctor.

Do not exceed the recommended dose.

HOW SUPPLIED

TriStart DHA™ is available as oval, brown softgel capsules with a yellow imprint "TriStart". They are available in child-resistant bottles containing 30 softgels (15370-250-30) and in a 3ct professional sample (15370-250-03).

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

TriStart DHA™ should be administered only under the direct supervision of a healthcare practitioner.

Avoid excessive heat, light and moisture.

Keep out of reach of children.

Tamper Evident

Do not use if seal is broken or missing.

Manufactured for:

CarWin Pharmaceutical Associates, LLC

Slidell, LA 70461

Rx

MADE IN CANADA

Rev. 05/2015

PRINCIPAL DISPLAY PANEL - 30 Capsule Bottle Label

15370-250-30

TriStart

DHA

PRENATAL SUPPLEMENT

*Dye Free, Lactose, Gluten
and Sugar Free*

Rx

30 Softgels

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15370-250-30



See attached labeling for complete product information.

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*Dye Free, Lactose, Gluten
 and Sugar Free*

30 Softgels

Rev. 05/2015

MADE IN CANADA **RX**

TRISTART DHA

ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacin, pyridoxine hydrochloride, levomefolate magnesium, folic acid, cyanocobalamin, iron pentacarbonyl, potassium iodide, magnesium oxide, doconexent, and icosapent capsule, liquid filled

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:15370-250 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------|
| ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 55 mg |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41) | CHOLECALCIFEROL | 1000 [iU] |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9) | .ALPHA.-TOCOPHEROL, D- | 15 [iU] |
| THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE HYDROCHLORIDE | 1.3 mg |
| RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 1.8 mg |
| NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A) | NIACIN | 5 mg |
| PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z) | PYRIDOXINE HYDROCHLORIDE | 35 mg |
| LEVOMEFOLATE MAGNESIUM (UNII: 1VZ62R081) (LEVOMEFOLIC ACID - UNII:8S95DH25XC) | LEVOMEFOLIC ACID | 600 ug |
| FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 400 ug |
| CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 14 ug |
| IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW895810WR) | FERROUS CATION | 31 mg |
| POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q) | IODIDE ION | 200 ug |
| MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM OXIDE | 30 mg |
| DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC) | DOCONEXENT | 200 mg |

| | | |
|--|-----------|-------|
| ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA) | ICOSAPENT | 15 mg |
|--|-----------|-------|

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GELATIN, UNSPECIFIED (UNII: 2G86QN327L) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0K00R) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| CARAMEL (UNII: T9D99G2B1R) | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | |
| ORANGE (UNII: 5EVU04N5QU) | |
| ETHYL VANILLIN (UNII: YC9ST449YJ) | |

Product Characteristics

| | | | |
|----------|-------|--------------|----------|
| Color | BROWN | Score | no score |
| Shape | OVAL | Size | 10mm |
| Flavor | | Imprint Code | TriStart |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:15370-250-30 | 30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/01/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-----------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER | | 06/01/2015 | |

Labeler - CarWin Pharmaceutical Associates, LLC (079217215)

Revised: 12/2019

CarWin Pharmaceutical Associates, LLC