

TENDERA-OB- ascorbic acid, cholecalciferol, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, levomefolate glucosamine, cyanocobalamin, iron pentacarbonyl, potassium iodide, magnesium oxide, zinc gluconate, cupric oxide, and doconexent capsule
BonGeo Pharmaceuticals, Inc.

Tendera-OB Prenatal Multivitamin + DHA

Supplement Facts		
Serving Size: 1 Softgel	Servings Per Container: 90	
	Amount Per Serving	% Daily Value in Pregnancy
Vitamin C (as Ascorbic Acid)	40 mg	67%
Vitamin D (as Cholecalciferol)	1000 IU	250%
Vitamin E (as d-Alpha- Tocopheryl Acetate)	10 IU	33%
Vitamin B ₁ (as Thiamine Mononitrate)	1.5 mg	88%
Vitamin B ₂ (as Riboflavin)	2 mg	100%
Vitamin B ₃ (as Niacin)	12 mg	60%
Vitamin B ₆ (as Pyridoxine HCl)	3 mg	120%
Folate (as 400 mcg Quatrefolic R ((6S-5-meth-yltetrahydrofolic acid, glucosamine salt, molar equivalent to 216 mcg of folic acid)) and 784 mcg of folic acid)	1 mg	125%
Vitamin B ₁₂ (as Cyanocobalamin 1%)	15 mcg	188%
Iron (as Iron Carbonyl Powder)	27 mg	150%
Iodine (as Potassium Iodide)	150 mcg	100%
Magnesium (as Magnesium Oxide)	10 mg	3%
Zinc (as Zinc Gluconate)	5 mg	33%
Copper (as Copper Oxide)	1 mg	50%
Docosahexaenoic Acid (DHA, Omega-3 Fish Oil)	205 mg	*

* Daily Value not established.

OTHER INGREDIENTS: Gelatin capsule (bovine gelatin, glycerin, purified water, Annatto and Caramel), yellow beeswax, sunflower, lecithin. **Contains: Fish.**

Tendera-OB™ Softgel capsules are dye free, lactose, gluten and sugar free. They do not contain any artificial flavors or sweeteners.

INDICATIONS

Tendera-OB™ is an orally administered multivitamin/multimineral fatty acid dietary supplement indicated to improve the nutritional status of women during pregnancy and in the postnatal period for both breastfeeding and non-breastfeeding mothers. Tendera-OB™ may also be beneficial in improving the nutritional status of women prior to conception.

CONTRAINDICATIONS

Tendera-OB™ 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. Decreased patient response to methotrexate may occur due to supplementation of folic acid. Furthermore, anticonvulsant medications may interfere with folate metabolism.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent disease.

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) 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. Supplemental intake of omega 3 fatty acids such as DHA above 2 grams per day is not recommended. In individuals with hypercalcemia or other conditions that may lead to hypercalcemia such as hyperparathyroidism and those that form calcium- containing kidney stones, Vitamin D supplementation should be used with caution. Elevated levels of calcium in blood and soft tissues may result from high doses of Vitamin D.

Use caution supplementing iodine in patients with overactive thyroid.

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 BonGeo Pharmaceuticals, Inc. at 1-844-640-7607.

DIRECTIONS

Adults

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

Not recommended for children under 12 years of age.

Do not exceed the recommended dose.

Tendera-OB™ should be administered under the direct supervision of a qualified healthcare practitioner.

HOW SUPPLIED

Tendera-OB™ is available as oval, dark red softgel capsules with an imprint "190". They are available in child-resistant bottles containing 90 softgels (52796-190-90). Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Avoid excessive heat, light and moisture.

Keep out of reach of children.

Tamper Evident

Do not use if seal is broken or missing.

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Manufactured for: BonGeo Pharmaceuticals, Inc.,
101 Eisenhower Parkway, Ste. 300 Roseland, NJ 07068
1-844-640-7607 | www.bongeopharma.net

PRINCIPAL DISPLAY PANEL - 90 Softgel Bottle Label

52796-190-90
90 SOFTGELS

Tendera-OB
Prenatal Multivitamin + DHA
DIETARY SUPPLEMENT

Quatrefolic®
Patent Ref.: U.S. Patent No. 7,947,662;
Other patents pending

Sugar Free,
Lactose Free and
Gluten Free

No Artificial Colors
or Flavors

BonGeo™
PHARMACEUTICALS

52796-190-90

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TENDERA-OB

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Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:52796-190
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	40 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	1000 [iU]
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	10 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	2 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	12 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	3 mg
LEVOMEFOLATE GLUCOSAMINE (UNII: Q65PL71Q1A) (LEVOMEFOLATE GLUCOSAMINE - UNII:Q65PL71Q1A)	LEVOMEFOLATE GLUCOSAMINE	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	15 ug
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	POTASSIUM IODIDE	150 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	10 mg
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	5 mg
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	205 mg

Inactive Ingredients

Ingredient Name	Strength
glycerin (UNII: PDC6A3C0OX)	
water (UNII: 059QF0KO0R)	
annatto (UNII: 6PQP1V1B6O)	
caramel (UNII: T9D99G2B1R)	
yellow wax (UNII: 2ZA36H0S2V)	

helianthus annuus whole (UNII: 17S27ZT6KR)

fish, unspecified (UNII: 1PIO77PW2X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:52796-190-90	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		03/19/2019	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	15 mm	
imprint		

Labeler - BonGeo Pharmaceuticals, Inc. (964822022)

Revised: 3/2019

BonGeo Pharmaceuticals, Inc.