Folivane™-OB *with Ascorbic Acid Precursors* Prescribing Information

Supplement Facts

Serving Size: 1 Capsule
Servings Per Container: 30

	Amount Per Serving	% DV for Pregnant and Lactating Women
Vitamin C (Ascorbic Acid)†	210 mg	175%
Thiamin (as Thiamine Mononitrate)	5 mg	357%
Riboflavin	5 mg	313%
Niacin	20 mg NE	111%
Vitamin B_6 (as Pyridoxine HCl)	25 mg	1250%
Folate	1667 mcg DFE (1000 mcg folic acid)	278%
Vitamin B_{12} (as Cyanocobalamin)	10 mcg	357%
Biotin	300 mcg	857%
Pantothenic Acid (as D-Calcium Pantothenate)	7 mg	100%
Iron (from Ferrous Fumarate and Polysaccharide Iron Complex)	85 mg	315%
Magnesium (as Magnesium Sulfate)	6.9 mg	2%
Zinc (as Zinc Sulfate)	18.2 mg	140%
Copper (as Copper Sulfate)	0.8 mg	62%
Manganese (as Manganese Sulfate)	1.3 mg	50%

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

Other Ingredients: Capsule (Hypromellose, Titanium Dioxide, FD&C Blue #1, FD&C Red #40) Microcrystalline Cellulose, Magnesium Stearate, and Fumed Silica.

Folivane™-OB is a prescription prenatal supplement designed to improve the nutritional status of women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Folivane™-OB may also be used to improve the nutritional status of women. **DO NOT ADMINISTER TO CHILDREN UNDER THE AGE OF 12.**

CONTRAINDICATIONS
Folivane™-OB is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemia. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

WARNINGS

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
General: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where B_{12} is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia assessment, such that hematologic remission can occur while neurological manifestations remain progressive.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic tests (e.g. troponin) and hormone test, 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.

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

Geriatric Use: Safety and effectiveness of this product have not been established in elderly patients.

DRUG INTERACTIONS
Folivane™-OB is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g. Aspirin, Heparin, Clopidogrel).

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 Folivane™-OB after meals may control occasional G.I. disturbances. Folivane™-OB is best absorbed when taken at bedtime.

OVERDOSAGE
Acute overdosage of iron may cause abdominal pain, nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other more chronic symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. Toxic effects are seen at 10-20 mg/kg elemental iron. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. Folivane™-OB 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
Folivane™-OB are blue opaque capsules imprinted with “T535” in white ink on both cap and body.

DIRECTIONS FOR USE
One (1) capsule daily, between meals, or as prescribed by a physician. **Do not exceed recommended dosage.**

HOW SUPPLIED
Folivane™-OB is dispensed in child-resistant bottles of 30 capsules.
Product Code: 13811-535-30

STORAGE: Store at 20°-25°C (68°-77°F), excursion permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP with a child-resistant closure.

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 at 1-877-482-3788 or FDA at 1-800-FDA-1088.

Customer Service: 1-877-482-3788 **Rev. 09/2019**

Manufactured for:
Trigen Laboratories, LLC
Bridgewater, NJ 08807

TRIGEN LABORATORIES