

## Folivane™ -Plus with Ascorbic Acid Precursors Prescribing Information

### Supplement Facts

Serving Size: 1 Capsule  
Servings Per Container: 90

	Amount Per Serving	% DV for Adults and Children over 12
Calories	0	
Total Carbohydrate	Less than 1 g	<1% <sup>†</sup>
Vitamin C (Ascorbic Acid)*	210 mg	233%
Thiamin (as Thiamine Mononitrate)	5 mg	417%
Riboflavin	5 mg	385%
Niacin	20 mg NE	125%
Vitamin B <sub>6</sub> (as Pyridoxine HCl)	25 mg	1471%
Folate	1667 mcg DFE (1000 mcg folic acid)	417%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	10 mcg	417%
Biotin	300 mcg	1000%
Pantothenic Acid (as D-Calcium Pantothenate)	7 mg	140%
Iron (from Ferrous Fumarate and Polysaccharide Iron Complex)	125 mg	694%

<sup>†</sup> Percent Daily Values are based on a 2,000 calorie diet

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

Folivane™ - Plus is a prescription multivitamin nutritional supplement indicated for improving nutritional status in adults with certainty illnesses or vitamin deficiencies. **DO NOT ADMINISTER TO CHILDREN UNDER THE AGE OF 12.**

#### CONTRAINDICATIONS

Folivane™ - Plus 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 anemias. 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<sub>12</sub> 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

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, taking Folivane™-Plus after meals may diminish occasional G.I. disturbances. Folivane™-Plus is best absorbed when taken at bedtime.

#### OVERDOSAGE

Acute overdose 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™-Plus should be stored beyond the reach of children to prevent against accidental iron poisoning. Keep this product 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.

#### DESCRIPTION

Folivane™ - Plus are maroon capsules imprinted "T539" in white.

#### DIRECTIONS FOR USE

Adults and children over 12 years of age: One (1) capsule daily, between meals, or as prescribed by a physician. Do not exceed recommended dosage.

#### HOW SUPPLIED

Folivane™-Plus is dispensed in child-resistant bottles of 90 capsules.

**Product Code: 13811-539-90**

**STORAGE:** Store at 20°-25°C (68°-77°F), excursion 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 at 1-888-9-TRIGEN (1-888-987-4436) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Customer Service: 1-888-987-4436**

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**Manufactured for:**  
Trigen Laboratories, LLC  
Bridgewater, NJ 08807

