

**FOLIVANE-PLUS WITH ASCORBIC ACID PRECURSORS- ascorbic acid, thiamine mononitrate, riboflavin, niacin, pyridoxine hcl, folic acid, cyanocobalamin, biotin, d-calcium pantothenate, ferrous fumarate, and polysaccharide iron complex capsule**  
**Trigen Laboratories, LLC**

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**Folivane-Plus with Ascorbic Acid Precursors**

**SUPPLEMENT FACTS**

# 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 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™ - Plus 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, taking Folivane™ - Plus after meals may diminish occasional G.I. disturbances. Folivane™ - Plus 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™ -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), 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.**



Ingredient Name	Basis of Strength	Strength
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	62.5 mg
<b>IRON</b> (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	62.5 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	210 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE	5 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	5 mg
<b>NIACIN</b> (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	10 ug
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-539-90	90 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		10/01/2017	

### Supplement Facts

**Serving Size :** \_\_\_\_\_ **Serving per Container :** \_\_\_\_\_

Amount Per Serving	% Daily Value
color	
imprint	
scoring	1

shape	
size (solid drugs)	23 mm

**Labeler** - Trigen Laboratories, LLC (830479668)

Revised: 1/2022

Trigen Laboratories, LLC