

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

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% [†]
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 ₆ (as Pyridoxine HCl)	25 mg	1471%
Folate	1667 mcg DFE (1000 mcg folic acid)	417%
Vitamin B ₁₂ (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%

[†] 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 B₁₂ 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

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.

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.

Customer Service: 1-888-987-4436

Rev. 07/2018

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



PRINCIPAL DISPLAY PANEL

Folivane-Plus with Ascorbic Acid Precursors 90ct
13811-539-90

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Manufactured for:
Trigen Laboratories, LLC
Bridgewater, NJ 08807
www.trigenlab.com

Rev. 07/2018

13811-539-90

Folivane™ - Plus
with Ascorbic Acid Precursors

IRON / FOLIC ACID /
MULTIVITAMIN SUPPLEMENT

90 CAPSULES

TRIGEN
LABORATORIES

Lot:
Exp:

**DESCRIPTION**

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

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

Peel label for prescribing and product information.

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

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:138 11-539
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	62.5 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	62.5 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	210 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE	5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	5 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBLAMIN (UNII: P6YC3EG204) (CYANOCOBLAMIN - UNII:P6YC3EG204)	CYANOCOBLAMIN	10 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	7 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:138 11-539-90	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: 5/2018

Trigen Laboratories, LLC