FOLIVANE-F- ferrous fumarate, iron, folic acid, ascorbic acid, and niacin capsule
Trigen Laboratories, LLC

Folivane™-F
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	%DV for Pregnant and Lactating Women
Vitamin C (Ascorbic acid)*	40 mg	44%	33%
Niacin (as Niacinamide Ascorbate)	3 mg NE	19%	17%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	417%	278%
Iron (from Ferrous Fumarate and Polysaccharide Iron Complex)	125 mg	694%	463%

*Also containing Ascorbic Acid Precursors as (1) Acid Metabolites including niacinamide ascorbate, 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: Microcrystalline Cellulose, Veggie Capsule (Hypromellose, Titanium Dioxide, FD&C Red #40, FD&C Blue #1), Magnesium Stearate, and Fumed Silica.

Folivane™-F is a professionally prescribed iron, folic acid, and vitamin supplement used to improve the nutritional status of patients with iron and/or folate deficiency anemia, including women in the prenatal and postnatal period. **Do not administer to children under the age of 12.**

CONTRAINDICATIONS

Folivane™-F is contraindicated in patients with a known hypersensitivity to any of the 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_{12} is deficient. Anemia requires appropriate investigation to determine its cause or causes. Periodic clinical and laboratory studies are considered essential. Blood tests including hemoglobin and hematocrit should be done to determine the adequacy of therapy. Folic acid should be used with care in the presence of peptic ulcer disease, regional enteritis, and ulcerative colitis. In doses above 0.1 mg daily, folic acid may obscure the diagnosis of pernicious anemia.

USAGE IN PREGNANCY

Before Folivane™-F is prescribed for megaloblastic anemia in pregnancy, appropriate diagnostic exclusion of Addisonian pernicious anemia (due to faulty or blocked absorption of vitamin B_{12}, or extrinsic factor or either a genetic, immunological or surgical basis) should be carried out.

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.

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, heartburn, and vomiting) occur occasionally, but are usually mild and may subside with continuation of therapy. Reducing the dose and administering it with meals will minimize these effects in the sensitive patient. Iron may turn stools black. This is a harmless effect that is a result of unabsorbed iron. Although the absorption of iron is best when taken between meals, giving Folivane™-F after meals may diminish occasional G.I disturbances. Folivane™-F 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™-F should be stored beyond the reach of children to prevent against accidental iron poisoning.

DESCRIPTION

Folivane™-F are maroon capsules imprinted "T538" in white.

DIRECTIONS FOR USE

One (1) capsule daily, between meals, or as directed by a physician. Do not exceed recommended dosage.

HOW SUPPLIED

Folivane™-F is supplied in bottle of 90 capsules.
Product Code: 13811-538-90

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 1-800-444-5164 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

PLR-FOLF-00001-2 Rev. 05/2023

Manufactured for:

Trigen Laboratories, LLC

Alpharetta, GA 30005

1-770-509-4500

PRINCIPAL DISPLAY PANEL - 90 Capsule Bottle Label

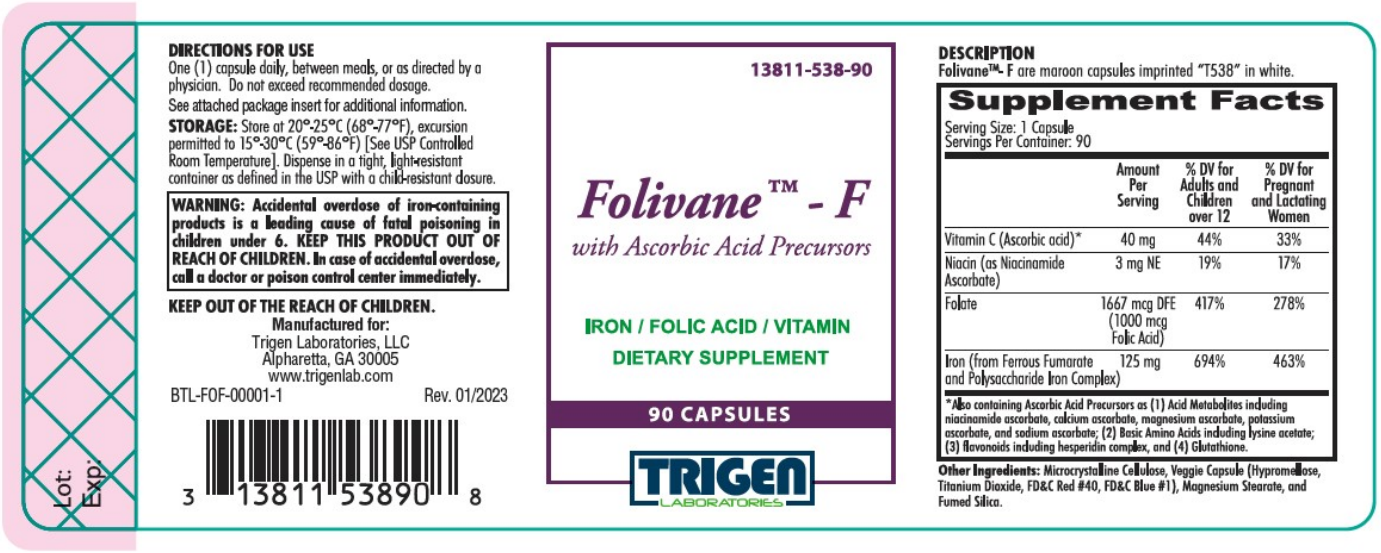
13811-538-90

Folivane™ - F
with Ascorbic Acid Precursors

IRON / FOLIC ACID / VITAMIN SUPPLEMENT CAPSULES

90 CAPSULES

TRIGEN
LABORATORIES



FOLIVANE-F

ferrous fumarate, iron, folic acid, ascorbic acid, and niacin capsule

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:13811-538
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	62.5 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	62.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	40 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	3 mg

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-538-90	90 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/01/2010	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
imprint		
scoring	1	
shape		
size (solid drugs)	20 mm	

Labeler - Trigen Laboratories, LLC (830479668)

Revised: 5/2023 Trigen Laboratories, LLC