

TRIGELS-F FORTE- folic acid, ascorbic acid, cyanocobalamin, and ferrous fumarate capsule

Trigen Laboratories, LLC

**Trigels-F
Forte**

DESCRIPTION

Supplement Facts

Serving Size: 1 Softgel Capsule

Servings Per Box: 100

	Amount per Serving	% DV Adults and Children 4 Years or More
Calories	10	
Total Fat	0.5 g	<1% [†]
Total Carbohydrate	< 1 g	<1% [†]
Vitamin C (Ascorbic Acid)	60 mg	67%
Folate	1667 mcg DFE (1000 mcg Folic Acid)	417%
Vitamin B ₁₂ (as Cyanocobalamin)	10 mcg	417%
Iron (as Ferrous Fumarate)	151 mg	839%

† Percent Daily Values (DV) are based on a 2,000 calorie diet.

Other Ingredients: Soybean Oil, Gelatin, Glycerin, Purified Water, Yellow Beeswax, Soy Lecithin, Ethyl Vanillin, Titanium Dioxide, FD&C Red #40, FD&C Yellow #5, FD&C Blue #1

THIS PRODUCT CONTAINS SOY.

Trigels-F Forte is a prescription vitamin used for the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation.

Inactive Ingredients

Soybean Oil, Gelatin, Glycerin, Purified Water, Yellow Beeswax, Lecithin, Ethyl Vanillin, Titanium Dioxide, FD&C Red #40, FD&C Yellow #5, FD&C Blue #1.

CONTRAINDICATIONS

Trigels-F Forte should not be used by patients with a known hypersensitivity to any of the listed ingredients including soy. All iron compounds are contraindicated in patients with hemochromatosis, hemosiderosis, or hemolytic anemias.

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

Do not exceed recommended dose. The type of anemia and the underlying cause or causes should be determined before starting therapy with Trigels-F Forte. Since the anemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

Folic Acid: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible patients. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid, as well as possibly the use of other forms of folates, including reduced folates. Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cyanocobalamin.

OVERDOSAGE

The clinical course of acute iron overdose can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, hypotension, tachycardia, metabolic acidosis, hyperglycemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma.

DESCRIPTION

Trigels-F Forte is a brown, oblong shaped softgel with laser imprinted "TL518" containing dark brown paste.

DIRECTIONS FOR USE

Take one softgel capsule by mouth daily or as directed by a physician.

HOW SUPPLIED

Trigels-F Forte is available in child resistant blister packs of 100 (10 x 10) softgel capsules.

Product Code: 13811-518-10

STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Protect from moisture and excessive heat.

KEEP THIS PRODUCT 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, LLC at 1-770-509-4500 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**PLR-TRIGELSF-00001-1
11/2021**

Rev.

**Manufactured for:
Trigen Laboratories, LLC
Alpharetta, GA 30005
www.trigenlab.com**



PRINCIPAL DISPLAY PANEL - 100 Softgel Blister Pack Carton

13811-518-10

Trigels-F
Forte

Softgels

100 SOFTGELS

TRIGEN
LABORATORIES



TRIGELS-F FORTE

folic acid, ascorbic acid, cyanocobalamin, and ferrous fumarate capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:13811-518
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Folic Acid (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	Folic Acid	1 mg
Ascorbic Acid (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cyanocobalamin (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	Cyanocobalamin	10 ug
Ferrous Fumarate (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	151 mg

Inactive Ingredients

Ingredient Name	Strength
soybean oil (UNII: 241ATL177A)	
gelatin (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C00X)	
water (UNII: 059QF0KO0R)	
yellow wax (UNII: 2ZA36H0S2V)	
lecithin, soybean (UNII: 1DI56QDM62)	
ethyl vanillin (UNII: YC9ST449YJ)	
titanium dioxide (UNII: 15FIX9V2JP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-518-10	10 in 1 CARTON		
1		100 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		08/01/2010	

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: 11/2021

Trigen Laboratories, LLC