

## TRIGELS-F FORTE Prescribing Information

### Supplement Facts

Serving Size: 1 Softgel Capsule  
Servings Per Box: 100

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

<sup>†</sup> 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.

#### 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 B<sub>12</sub> 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 overdosage 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 1-888-9-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  
[www.trigenlab.com](http://www.trigenlab.com)

