TriphroCaps Softgels Prescribing Information

Supplement Facts

Serving Size: 1 Softgel Capsule
Servings Per Container: 100

	Amount Per Serving	% Daily Value for Adults & Children ≥ 4 years
Vitamin C (Ascorbic Acid)	100 mg	111%
Thiamin (as Thiamine Mononitrate)	1.5 mg	125%
Riboflavin	1.7 mg	131%
Niacin (as Niacinamide)	20 mg NE	125%
Vitamin B_6 (as Pyridoxine HCl)	10 mg	588%
Folate	1667 mcg DFE (1000 mcg folic acid)	417%
Vitamin B_{12} (as Cyanocobalamin)	6 mcg	250%
Biotin	150 mcg	500%
Pantothenic Acid (as d-Calcium Pantothenate)	5 mg	100%

Other Ingredients: Soybean Oil, Bovine Gelatin, Glycerin, Water, Yellow Beeswax, Lecithin, Titanium Dioxide, FD&C Red #40, Ethyl Vanillin, FD&C Yellow #5, FD&C Yellow #6, and Iron Oxide Red

THIS PRODUCT CONTAINS SOY.

TriphroCaps are an orally administered prescription vitamin used for the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation.

CONTRAINDICATIONS
TriphroCaps are contraindicated in patients with a known hypersensitivity to any of the ingredients including soy.

PRECAUTIONS
Folic acid alone is an improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B_{12} is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive.

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

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Safety and effectiveness in elderly patients have not been established.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic tests (e.g. troponin) and hormone tests, and may 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.

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.

DRUG INTERACTIONS
TriphroCaps 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
Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DESCRIPTION
TriphroCaps are red, oval softgel capsules, imprinted with "T9".

DIRECTIONS FOR USE
Take one softgel capsule daily or as prescribed by a physician. On dialysis days, take one TriphroCaps softgel after dialysis.

HOW SUPPLIED
TriphroCaps are supplied in bottles of 100 softgel capsules.
Product Code: 13811-525-01

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, LLC at 1-877-482-3788 or FDA at 1-800-FDA-1088.

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Customer Service: 1-877-482-3788

Manufactured for:
Trigen Laboratories, LLC
Bridgewater, NJ 08807

TRIGEN LABORATORIES