

TRIPHROCAPS- folic acid, ascorbic acid, niacinamide, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, calcium pantothenate, and biotin capsule
Trigen Laboratories, LLC

TriphroCaps
Softgels

SUPPLEMENT FACTS

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 B₆ (as Pyridoxine HCl)	10 mg	588%
Folate	1667 mcg DFE (1000 mcg folic acid)	417%
Vitamin B₁₂ (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 B₁₂ 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 1-770-509-4500 or FDA at 1-800-FDA-1088.

PLR-TRIPHRO-00001-1 Rev. 11/2021

Manufactured for:

Trigen Laboratories, LLC

Alpharetta, GA 30005



PRINCIPAL DISPLAY PANEL - 100 Softgel Bottle Label

13811-525-01

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Softgels**

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**TRIGEN
LABORATORIES**

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PLR-TRIPHRO-00001-1 Rev. 11/2021

Manufactured for:
Trigen Laboratories, LLC
Alpharetta, GA 30005



13811-525-01

TriphroCaps

Softgels

Dietary Supplement

100 SOFTGELS

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THIS PRODUCT CONTAINS SOY.

Peel to reveal prescribing and product information.

Lot: 3

Exp: 4



TRIPHROCAPS

folic acid, ascorbic acid, niacinamide, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, calcium pantothenate, and biotin capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:13811-525
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	100 mg
niacinamide (UNII: 25X51I8RD4) (niacinamide - UNII:25X51I8RD4)	niacinamide	20 mg
thiamine mononitrate (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	Thiamine	1.5 mg
riboflavin (UNII: TLM2976OFR) (riboflavin - UNII:TLM2976OFR)	riboflavin	1.7 mg
pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	pyridoxine Hydrochloride	10 mg
cyanocobalamin (UNII: P6YC3EG204) (cyanocobalamin - UNII:P6YC3EG204)	cyanocobalamin	6 ug
calcium pantothenate (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737, CALCIUM CATION - UNII:2M83C4R6ZB)	PANTOTHENIC ACID	5 mg
biotin (UNII: 6SO6U10H04) (biotin - UNII:6SO6U10H04)	biotin	150 ug

Inactive Ingredients

Ingredient Name	Strength
soybean oil (UNII: 241ATL177A)	
GELATIN TYPE B BOVINE (160 BLOOM) (UNII: 1T8387508X)	
glycerin (UNII: PDC6A3C00X)	

water (UNII: 059QF0KO0R)	
yellow wax (UNII: 2ZA36H0S2V)	
titanium dioxide (UNII: 15FIX9V2JP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
ethyl vanillin (UNII: YC9ST449YJ)	
FD&C yellow No. 5 (UNII: I753WB2F1M)	
FD&C yellow No. 6 (UNII: H77VEI93A8)	
ferric oxide red (UNII: 1K09F3G675)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:13811-525-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/27/2016	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
imprint		
scoring	1	
shape		
size (solid drugs)	13 mm	

Labeler - Trigen Laboratories, LLC (830479668)

Revised: 11/2021

Trigen Laboratories, LLC