TRIPHROCAPS - folic acid, as corbic acid, niacinamide, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, calcium pantothenate, and biotin capsule State of Florida DOH Central Pharmacy

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TriphroCaps Softgels

**Rx Only** 

#### **DESCRIPTION**

TriphroCaps are an orally administered prescription vitamin for the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation. TriphroCaps are red, oval softgel capsules, imprinted "T9."

Supplement Facts Servings per Bottle: 100		
Serving Size: 1 Softgel Capsule	%DV Adults 8	k Children
Each Softgel Capsule contains	4 Year	s or More
Folate	1 mg	250%
Vitamin C (ascorbic acid)	100 mg	167%
Niacin (niacinamide)	20 mg	100%
<b>Thiamine</b> (thiamine mononitrate)	1.5 mg	100%
Riboflavin	1.7 mg	100%
<b>Vitamin B</b> $_{6}$ (pyridoxine HCl)	10 mg	500%
<b>Vitamin B<sub>12</sub></b> (cyanocobalamin)	6 mcg	100%
Pantothenic Acid (calcium pantothenate)	5 mg	<b>50</b> %
Biotin	150 mcg	<b>50</b> %

*Inactive Ingredients:* Soybean Oil, Gelatin, Glycerin, Purified Water, Yellow Bees Wax, Lecithin, Titanium Dioxide, FD&C Red #40, Ethyl Vanillin, FD&C Yellow #5, FD&C Yellow #6, Iron Oxide.

### INDICATIONS AND USAGE

TriphroCaps are indicated for the supplemental requirements of patients with nutritional deficiencies or are in need of nutritional supplementation.

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

#### CONTRAINDICATIONS

TriphroCaps is contraindicated in patients with a known hypersensitivity to any of the ingredients.

#### **WARNINGS**

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 neurological manifestations remain progressive.

#### THIS PRODUCT CONTAINS SOY.

#### **PRECAUTIONS**

#### **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

#### Geriatric Use

Clinical studies on this product have not been performed in sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for elderly patients should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function of concomitant disease or other drug therapy.

#### ADVERSE REACTIONS

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

#### DOSAGE AND ADMINISTRATION

Take one TriphroCaps softgel 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.

They are supplied by **State of Florida DOH Central Pharmacy** as follows:

NDC	Quantity/Form	Color	Source Prod. Code
53808-0987-1	30 Capsules in a Blister Pack	RED	13811-525

#### STORAGE

Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP controlled room temperature].

Call your doctor about side effects. You may report side effects by calling 888 9 TRIGEN (888-987-4436).

#### KEEP OUT OF REACH OF CHILDREN

## **Rx Only**

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. There are no implied or explicit claims on therapeutic equivalence.

#### Manufactured for:

TRIGEN Laboratories, Inc., Sayreville, NJ 08872

www.trigenlab.com

This Product was Repackaged By:

**State of Florida DOH Central Pharmacy** 

104-2 Hamilton Park Drive Tallahassee, FL 32304 United States

## **PACKAGE LABEL**

Label Image for **53808-0987** 



## **TRIPHROCAPS**

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

<b>Product Information</b>			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:53808-0987(NDC: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: 25X5118 RD4) (NIACINAMIDE - UNII:25X5118 RD4)	NIACINAMIDE	20 mg	
THIAMINE MONONITRATE (UNII: 8K0 I0 49 19 X) (THIAMINE ION - UNII: 4ABT0 J9 45 J)	THIAMINE	1.5 mg	
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg	
<b>PYRIDO XINE HYDRO CHLO RIDE</b> (UNII: 68 Y4CF58 BV) (PYRIDO XINE - UNII: KV2JZ1BI6Z)	PYRIDO XINE HYDROCHLORIDE	10 mg	
CYANO CO BALAMIN (UNII: P6 YC3EG204) (CYANO COBALAMIN - UNII:P6 YC3EG204)	CYANOCOBALAMIN	6 ug	
CALCIUM PANTO THENATE (UNII: 568 ET80 C3D) (PANTO THENIC ACID - UNII: 19 F5HK2737)	PANTOTHENIC ACID	5 mg	
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	150 ug	

Inactive Ingredients	
Ingredient Name	Strength

SOYBEAN OIL (UNII: 241ATL177A)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
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)	

I	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NHRIC:53808-0987-1	30 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		0 1/0 1/20 13	

Supplement Fa	acts	
Serving Size :		Serving per Container :
	Amount Per Serving	% Daily Value
color		
shape		
scoring	1	
imprint		
size (solid drugs)	13 mm	

# Labeler - State of Florida DOH Central Pharmacy (829348114)

Establishment			
Name	Address	ID/FEI	Business Operations
State of Florida DOH Central Pharmacy		829348114	repack(53808-0987)

Revised: 4/2014