

TRONVITE- vitamin c, thiamine, riboflavin, niacin, vitamin b6, folic acid, vitamin b12, biotin, pantothenic acid tablet, coated
AMELLA PHARMA, LLC

TRONVite

TRONVITE Tablets Dietary Supplement
Dispensed by Prescription†

Supplement Facts		
Serving Size: 1 Tablet		Serving Per Container: 30
Amount Per Serving		% Daily Value
Vitamin C (as ascorbic Acid)	100 mg	111%
Thiamine (as thiamine mononitrate)	1.5 mg	125%
Riboflavin	1.7 mg	131%
Niacin (as niacinamide)	20 mg	125%
Vitamin B6 (as pyridoxine HCl)	10 mg	588%
Folic Acid (1mg Folic Acid)	1 mg	417%
Vitamin B12 (as methylcobalamin)	6 mcg	250%
Biotin	300 mcg	1000%
Pantothenic Acid (as d-calcium pantothenate)	10 mg	200%

OTHER INGREDIENTS: microcrystalline cellulose, croscarmellose sodium, pharmaceutical glaze, mono- and diglycerides, starch, calcium stearate.

DESCRIPTION

TRONVITE Tablets is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

TRONVITE is a small, round, yellow, clear-coated tablet, with debossed "A" on one side.

CONTRAINDICATIONS

This product is contraindicated in patients with known hypersensitivity to any of the ingredients.

PRECAUTIONS

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

TRONVITE Tablets should only be used under the direction and supervision of a licensed medical practitioner. Use with caution in patients that may have a medical condition, are pregnant, lactating, trying to conceive, under the age of 18, or taking medications.

Folic acid supplementation may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations progress.

KEEP OUT OF THE REACH OF CHILDREN.

Pregnancy and Lactation:

TRONVITE Tablets is not intended for use in pregnant or lactating patients

ADVERSE REACTIONS

Allergic sensitizations have been reported following oral administration of folic acid. Consult your physician immediately if adverse side effects occur.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 tablet by mouth once or twice daily or as prescribed by a licensed medical practitioner.

HOW SUPPLIED HEALTH CLAIM:

TRONVITE Tablets are supplied as a small, round, yellow, clear-coated tablet, with debossed "A" on one side. TronVite Tablets is available as the following:

72287-121-30* 30ct bottle

Store at 20° to 25°C (68° to 77°F; excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]

Manufactured for:
Amella Pharma, LLC
E Brunswick, NJ 08816

Call your doctor for medical advice about side effects. You may report side effects to Amella Pharma, LLC at 1-844-385-0850.

Issued: 09/2018 AP1002v2

*Amella Pharma does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

† This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760). The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription (Rx). This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.

Packaging

USUAL DOSAGE: Usual adult dose is 1 tablet by mouth once daily or as prescribed by a licensed medical practitioner. If you are pregnant or nursing, ask a healthcare professional prior to using. Consult your physician immediately if adverse side effects occur.

KEEP OUT OF THE REACH OF CHILDREN.

STORAGE: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature.]

02/2020 AP-1001v3



Manufactured for: Amella Pharma, LLC
East Brunswick, NJ 08816 1-844-385-0850

72287-0121-30

TronVITE Tablets

C B1 B2 B3 B5 B6 B7 B12 FA

DIETARY SUPPLEMENT

30 Tablets Rx Only

Amount Per Serving:	Servings Per Container: 30	
		% Daily Value
Vitamin C (as ascorbic acid).....	100 mg	111%
Thiamine (as thiamine mononitrate).....	1.5 mg	125%
Riboflavin.....	1.7 mg	131%
Niacin (as niacinamide).....	20 mg	125%
Vitamin B6 (as pyridoxine HCl).....	10 mg	588%
Folate (1mg Folic Acid).....	1666 mcg DFE	417%
Vitamin B12 (as methylcobalamin).....	6 mcg	250%
Biotin.....	300 mcg	1000%
Pantothenic Acid (as D-calcium pantothenate).....	10 mg	200%

OTHER INGREDIENTS: microcrystalline cellulose, croscarmellose sodium, pharmaceutical glaze, mono- and diglycerides, starch, calcium stearate.

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VARNISH FREE ZONE FOR EXPIRATION AND LOT #

TRONVITE

vitamin c, thiamine, riboflavin, niacin, vitamin b6, folic acid, vitamin b12, biotin, pantothenic acid tablet, coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:72287-121
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	6 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	10 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SHELLAC (UNII: 46N107B71O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STARCH, CORN (UNII: O8232NY3SJ)	
CALCIUM STEARATE (UNII: 776XM7047L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72287-121-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		05/23/2018	

Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	11 mm	
scoring	1	
imprint		

Labeler - AMELLA PHARMA, LLC (081189492)

Establishment

Name	Address	ID/FEI	Business Operations
Hillestad Pharmaceuticals USA		029291085	manufacture(72287-121)

Revised: 9/2020

AMELLA PHARMA, LLC