

**VOL-PLUS- folic acid, ascorbic acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, niacinamide, vitamin a acetate, .beta.-carotene, cholecalciferol, .alpha.-tocopherol acetate, dl-, cupric oxide, zinc oxide, ferrous fumarate, and calcium sulfate tablet, coated**

**Trigen Laboratories, LLC**

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**Vol-Plus  
Tablets**

**SUPPLEMENT FACTS**

# Supplement Facts

Serving Size: 1 Tablet

Servings per Container: 100

	Amount per Serving	%DV* for Adults and Children ≥4 years	% DV* for Pregnant and Lactating Women
Vitamin A (as Vitamin A Acetate and Beta-Carotene)	1,200 mcg RAE (4000 IU)	133%	92%
Vitamin C (Ascorbic Acid)	120 mg	133%	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	50%	67%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	10 mg** (22 IU)	67%	53%
Thiamin (as Thiamine Mononitrate)	1.8 mg	150%	129%
Riboflavin	3 mg	231%	188%
Niacin (as Niacinamide)	20 mg NE	125%	111%
Vitamin B <sub>6</sub> (as Pyridoxine HCl)	10 mg	588%	500%
Folate	1667 mcg DFE (1,000 mcg Folic Acid)	417%	278%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	12 mcg	500%	429%
Calcium (as Calcium Sulfate)	200 mg	15%	15%
Iron (as Ferrous Fumarate)	27 mg	150%	100%
Zinc (as Zinc Oxide)	25 mg	227%	192%
Copper (as Cupric Oxide)	2 mg	222%	154%
*Daily Value (DV)			
**Equal to mg alpha-tocopherol			

**Other Ingredients:** Microcrystalline Cellulose, Beige Color Coating (Hydroxypropylmethyl Cellulose, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, FD&C Yellow #6 Lake, FD&C Blue #2 Lake), Pregelatinized Starch, Croscarmellose Sodium, Di Calcium Phosphate, Magnesium Stearate, Stearic Acid, Fumed Silica, Ascorbyl Palmitate.

# Supplement Facts

Serving Size: 1 Tablet

Servings per Container: 500

	Amount per Serving	%DV* for Adults and Children ≥4 years	% DV* for Pregnant and Lactating Women
Vitamin A (as Vitamin A Acetate and Beta-Carotene)	1,200 mcg RAE (4000 IU)	133%	92%
Vitamin C (Ascorbic Acid)	120 mg	133%	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	50%	67%
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\*Daily Value (DV)

\*\*Equal to mg alpha-tocopherol

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Vol-Plus is a prescription vitamin for the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation, including women prior to conception, throughout pregnancy, and in the postnatal period for both lactating and non-lactating mothers.

## CONTRAINDICATIONS

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

**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

General: Folic acid alone is an 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.

## DRUG INTERACTIONS

Pyridoxine hydrochloride should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine hydrochloride. However, pyridoxine hydrochloride may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. 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, as well as possibly the use of other forms of folates - including reduced folates.

Paresthesia, somnolence, nausea and headaches have been reported with pyridoxine hydrochloride.

Mild transient diarrhea, polycythemia vera, itching, transitory exanthema and the feeling of swelling of the entire body have been associated with cyanocobalamin.

## Ferrous Fumarate

Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and subside with continuation of therapy and physician encouragement. Although, the absorption of iron is best when taken between meals, occasional gastrointestinal disturbances may be controlled giving Vol-Plus shortly after meals.

## DESCRIPTION

Vol-Plus is an oval, beige tablet imprinted with "TL519".

## DIRECTIONS FOR USE

Take one tablet daily or as prescribed by a physician.

## HOW SUPPLIED

Vol-Plus is supplied in bottles of 100 tablets and bottles of 500 tablets.

Product Code: 13811-519-10 (Bottles of 100 tablets)

Product Code: 13811-519-50 (Bottles of 500 tablets)

## **STORAGE**

Store at room temperature 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [see USP controlled room temperature]. Dispense in a tight, light resistant container as defined by the USP with a child resistant closure. Protect from light and moisture and avoid excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

## **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 1-888-9-TRIGEN (1-888-987-4436) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

**Rev. 07/2018**

**Customer Service: 1-888-987-4436**



**Manufactured for:  
Trigen Laboratories, LLC  
Bridgewater, NJ 08807  
[www.trigenlab.com](http://www.trigenlab.com)**

## **PRINCIPAL DISPLAY PANEL - 500 Tablet Bottle Label**

**13811-519-50**

**Vol-Plus  
Tablets**

**500 TABLETS**

**TRIGEN  
LABORATORIES**

**STORAGE:** Store at room temperature 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Dispense in a tight, light resistant container as defined by the USP with a child resistant closure. Protect from light and moisture and avoid excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

**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.

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).

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Rev. 07/2018



Lot:  
Exp:

3 13811151950 1

13811-519-50

# Vol-Plus Tablets

DIETARY SUPPLEMENT

500 TABLETS



**DESCRIPTION**

Vol-Plus is an oval, beige tablet imprinted with "TL519".

## Supplement Facts

Serving Size: 1 Tablet  
Servings per Container: 500

	Amount per Serving	% DV* for Adults and Children ≥4 years	% DV* for Pregnant and Lactating Women
Vitamin A (as Vitamin A Acetate and Beta-Carotene)	1,200 mcg RAE (4000 IU)	133%	92%
Vitamin C (Ascorbic Acid)	120 mg	133%	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	50%	67%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	10 mg** (22 IU)	67%	53%
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Folate	1667 mcg DFE (1,000 mcg Folic Acid)	417%	278%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	12 mcg	500%	429%
Calcium (as Calcium Sulfate)	200 mg	15%	15%
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Zinc (as Zinc Oxide)	25 mg	227%	192%
Copper (as Cupric Oxide)	2 mg	222%	154%

\*Daily Value (DV)

\*\*Equal to mg alpha-tocopherol

**Other Ingredients:** Microcrystalline Cellulose, Beige Color Coating (Hydroxypropylmethyl Cellulose, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, FD&C Yellow #6 Lake, FD&C Blue #2 Lake), Pregelatinized Starch, Croscarmellose Sodium, Di Calcium Phosphate, Magnesium Stearate, Stearic Acid, Fumed Silica, Ascorbyl Palmitate.

Peel label for prescribing and product information.

### PRINCIPAL DISPLAY PANEL- 100 Tablet Bottle Label

13811-519-10

Vol-Plus  
Tablets

100 TABLETS

TRIGEN  
LABORATORIES

**STORAGE:** Store at room temperature 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature]. Dispense in a tight, light resistant container as defined by the USP with a child resistant closure. Protect from light and moisture and avoid excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

**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.

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).

**KEEP OUT OF REACH OF CHILDREN.**

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[www.trigenlab.com](http://www.trigenlab.com)

Rev. 07/2018



Lot:  
Exp:

3 13811151910 5

13811-519-10

# Vol-Plus Tablets

DIETARY SUPPLEMENT

100 TABLETS



**DESCRIPTION**

Vol-Plus is an oval, beige tablet imprinted with "TL519".

## Supplement Facts

Serving Size: 1 Tablet  
Servings per Container: 100

	Amount per Serving	% DV* for Adults and Children ≥4 years	% DV* for Pregnant and Lactating Women
Vitamin A (as Vitamin A Acetate and Beta-Carotene)	1,200 mcg RAE (4000 IU)	133%	92%
Vitamin C (Ascorbic Acid)	120 mg	133%	100%
Vitamin D (as Cholecalciferol)	10 mcg (400 IU)	50%	67%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	10 mg** (22 IU)	67%	53%
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\*Daily Value (DV)

\*\*Equal to mg alpha-tocopherol

**Other Ingredients:** Microcrystalline Cellulose, Beige Color Coating (Hydroxypropylmethyl Cellulose, Polyvinyl Alcohol, Titanium Dioxide, Polyethylene Glycol, Talc, FD&C Yellow #6 Lake, FD&C Blue #2 Lake), Pregelatinized Starch, Croscarmellose Sodium, Di Calcium Phosphate, Magnesium Stearate, Stearic Acid, Fumed Silica, Ascorbyl Palmitate.

Peel label for prescribing and product information.

## VOL-PLUS

folic acid, ascorbic acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, niacinamide, vitamin a acetate, .beta.-carotene, cholecalciferol, .alpha.-tocopherol acetate, dl-, cupric oxide, zinc oxide, ferrous fumarate, and calcium sulfate tablet, coated

## Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:138 11-519
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE	1.84 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
<b>VITAMIN A ACETATE</b> (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	500 [iU]
<b>.BETA.-CAROTENE</b> (UNII: 01YAE03M7J) (.BETA.-CAROTENE - UNII:01YAE03M7J)	.BETA.-CAROTENE	3500 [iU]
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	10 mg
<b>CUPRIC OXIDE</b> (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	25 mg
<b>FERROUS FUMARATE</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
<b>CALCIUM SULFATE</b> (UNII: WAT0DDB505) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM SULFATE	200 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:138 11-519-01	1000 in 1 BOTTLE, PLASTIC		

2	NHRIC:138 11-519-10	100 in 1 BOTTLE, PLASTIC		
3	NHRIC:138 11-519-50	500 in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		06/01/2010	02/28/2021

## Supplement Facts

**Serving Size :** **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
imprint		
scoring	1	
shape		
size (solid drugs)	22 mm	

**Labeler** - Trigen Laboratories, LLC (830479668)

Revised: 9/2018

Trigen Laboratories, LLC