

**TM-VITE RX- ascorbic acid, thiamine monoitrate, riboflavin, niacinamide, pyridoxine hcl, cyanocobalamin, biotin, calcium panthothenate tablet  
Singular Dreamer, Ltd dba True Marker**

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**Statement of identity**

Prescription Folic Acid-Containing Dietary Supplement

**Warnings**

**High levels of folic acid may, especially in older adults, hide signs of vitamin B-12 deficiency (such as pernicious anemia, a condition that can cause nerve damage).**

**PATIENT INFORMATION**

TM-Vite Rx is a prescription vitamin for use only under the direction and supervision of a licensed physician.

**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.

Drugs which may interact with folate include:

- Antiepileptic drugs (AED): The AED class including, but not limited to, phenytoin, carbamazepine, primidone, valproic acid, phenobarbital and lamotrigine have been shown to impair folate absorption and increase the metabolism of circulating folate. Additionally, concurrent use of folic acid has been associated with enhanced phenytoin metabolism, lowering the levels of this AED in the blood and allowing breakthrough seizures to occur.
- Capecitabine: Folinic acid (5-formyltetrahydrofolate) may increase the toxicity of Capecitabine.
- Cholestyramine: Reduces folic acid absorption and reduces serum folate levels.
- Colestipol: Reduces folic acid absorption and reduces serum folate levels.
- Cycloserine: Reduces folic acid absorption and reduces serum folate levels.
- Dihydrofolate Reductase Inhibitors (DHFRIs): DHFRIs including aminopterin, methotrexate, pyrimethamine, triamterene, and trimethoprim, block the conversion of folic acid to its active forms, and lower plasma and red blood cell folate levels.
- Fluoxetine: Fluoxetine exerts a noncompetitive inhibition of 5-methyltetrahydrofolate active transport in the intestine.
- Isotretinoin: Reduced folate levels have occurred in some patients taking isotretinoin.
- Nonsteroidal Anti-inflammatory Drugs (NSAIDs): NSAIDs, including ibuprofen, naproxen, indomethacin and sulindac, have been shown to inhibit some folate-dependent enzymes in laboratory experiments.
- Oral Contraceptives: Serum folate levels may be depressed by oral contraceptive therapy.

- Methylprednisolone: Reduced serum folate levels have been noted after treatment with methylprednisolone.
- Pancreatic Enzymes: Reduced folate levels have occurred in some patients taking pancreatic extracts.
- Pentamidine: Reduced folate levels have been seen with prolonged intravenous pentamidine treatment.
- Smoking and alcohol: Reduced serum folate levels have been noted.
- Sulfasalazine: Inhibits the absorption and metabolism of folic acid.
- Metformin treatment in patients with type 2 diabetes decreases serum folate.
- Warfarin can produce significant impairment in folate status after a 6-month therapy.

## **SIDE EFFECTS**

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

**Keep out of reach of children**

## ***Directions***

1 tablet daily with or without food or as prescribed by a licensed medical practitioner.

## **Safe handling and warning section**

Store at 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30°C (59° to 86°F) Protect from light and moisture. Dispense in a tight, light-resistant container. Notice: Contact with moisture may produce surface discoloration or erosion.

**Call your licensed medical practitioner about side effects. You may report side effects by calling True Marker at 1-888-811-2634 or FDA at 1-800-FDA-1088.**

## **Product label**

NDC 83035-1215-09



# TM-Vite RX

Prescription Folic Acid-Containing  
Dietary Supplement



EXP DATE:

90 Tablets



**true  
marker**

## Supplement Facts

Serving Size 1 Tablet

	Amount Per Serving	% Daily Value
Vitamin C (ascorbic acid)	60mg	100%
Vitamin B1 (thiamine monoitrate)	1.5mg	100%
Vitamin B2 (riboflavin)	1.7mg	100%
Niacinamide (vitamin B3)	20mg	100%
Vitamin B6 (pyridoxine HCl)	10mg	500%
Folic Acid	1mg	250%
Vitamin B12 (cyanocobalamin)	6mcg	100%
Biotin	300mcg	100%
Pantothenic Acid (calcium panthothenate)	10mg	100%

**Other Ingredients:** Dicalcium Prosomata, Microcrvstalin Celulose, Stearic Acid, Magnesium Stearate, Croscarmellicse Sodium, Silica, Hypromellose, TitaniumDioxide, and FD&C Yellow #5.

Keep out of reach of children

Manufactured for:  
Singular Dreamer, Ltd. dba True Marker  
Glendale, CA 91205  
Tel. 888-811-2634

## TM-VITE RX

ascorbic acid, thiamine monoitrate, riboflavin, niacinamide, pyridoxine hcl, cyanocobalamin, biotin, calcium panthothenate tablet

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:83035-1215
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
<b>NIACINAMIDE</b> (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	10 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	6 ug
<b>BIOTIN</b> (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	300 ug
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	10 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE MONONITRATE	1.5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE 302</b> (UNII: 91B875MM4H)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:83035-1215-9	90 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		05/05/2023	

### Supplement Facts

**Serving Size :** \_\_\_\_\_ **Serving per Container :** \_\_\_\_\_

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	5 mm	
scoring	1	

**Labeler** - Singular Dreamer, Ltd dba True Marker (129504103)

**Registrant** - Singular Dreamer, Ltd dba True Marker (129504103)

Revised: 5/2023

Singular Dreamer, Ltd dba True Marker