

**ZYVIT- ascorbic acid, cholecalciferol, thiamin hcl, pyridoxal 5 phosphate, folic acid, methylcobalamin, adenine dinucleotide, ubiquinone tablet**  
**TMIG Inc.**

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**HEALTH CLAIM:**

Zyvit Tablets Dietary Supplement

Dispensed by Prescription<sup>†</sup>

**Supplement Facts**

<b>Serving Size: 1 Tablet</b> Servings per Bottle: 30		
<b>Amount Per Serving:</b>	<b>% Daily Value</b>	
Vitamin C (as ascorbic acid)	125 mg	208%
Vitamin D3 (as cholecalciferol)	500 IU	125%
Thiamin (Vitamin B1 as thiamin HCl)	25 mg	1,667%
Vitamin B6 (as pyridoxal 5' phosphate)	12.5 mg	625%
Folic Acid	1 mg	250%
Vitamin B12 (as methylcobalamin)	1 mg	16,667%
NADH (reduced nicotinamide-adenine dinucleotide)	5 mg	*
CoEnzyme Q-10 (ubiquinone)	50 mg	*
<i>*Daily Values (DV) not established.</i>		

**OTHER INGREDIENTS:** cellulose, magnesium stearate, and silicon dioxide.

**DESCRIPTION:**

Zyvit 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.

**WARNING AND PRECAUTIONS**

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

Zyvit 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.

**Pregnancy and Lactation**

Zyvit is not intended for use in pregnant or lactating patients.

**DOSAGE & ADMINISTRATION**

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

**HOW SUPPLIED HEALTH CLAIM:**

Zyvit tablets are supplied as tan, oblong shaped tablets with no imprint in a child-resistant bottle of 30ct. (69176-600-30\*)

Dispensed by Prescription†

\*TMIG Inc. 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).<sup>1-3</sup> 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.

1. Federal Register Notice of August 2, 1973 (38 FR 20750)
2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044)
3. Federal Register Notice of March 5, 1996 (61 FR 8760)

**STORAGE AND HANDLING:**

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

Protect from heat, light and moisture.

**KEEP OUT OF THE REACH OF CHILDREN.**

**Tamper Evident:** Do not use if seal is broken or missing.

Dosage: Take this medication by mouth, usually once daily or as directed by your physician. Do not take more than the recommended dosage. If you are uncertain about any of the information, consult your doctor or pharmacist.

KEEP OUT OF REACH OF CHILDREN.

STORAGE: Store at room temperature (20 -25 degrees Celsius 68-77 F)

Manufactured for and distributed by TMIG Inc. Marietta, Ga.

Lot no  
Exp Date



69176-600-30



69176-600-30

# Zyvit

Dietary Supplement Tablets

DISPENSED BY PRESCRIPTION ONLY

30 tablets

### Supplement Facts

Amount per serving	% Daily Value
Serving Size: 1 tablet Servings per container: 30	
Vitamin C (as ascorbic acid)	125mg 208%
Vitamin D3 (as cholecalciferol)	500IU 125%
Thiamin (Vitamin B1 as thiamin HCl)	25mg 1667%
Vitamin B6 (as pyridoxal 5' phosphate)	12.5mg 625%
Folic Acid	1mg 250%
Vitamin B12 (as methylcobalamin)	1mg 16667%
NADH (reduced nicotinamide-adenine dinucleotide)	5mg *
CoEnzyme Q-10 (ubiquinone)	60mg *

\*Daily Values (DV) not established

OTHER INGREDIENTS cellulose, magnesium stearate and silicon dioxide.

ascorbic acid, cholecalciferol, thiamin hcl, pyridoxal 5 phosphate, folic acid, methylcobalamin, adenine dinucleotide, ubiquinone tablet

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:69176-600
<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	125 mg
<b>cholecalciferol</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	cholecalciferol	500 [iU]
<b>THIAMINE HYDROCHLORIDE</b> (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	25 mg
<b>PYRIDOXAL PHOSPHATE ANHYDROUS</b> (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	12.5 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
<b>METHYLCOBALAMIN</b> (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
<b>NADH</b> (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	5 mg
<b>COENZYME Q10, (2Z)-</b> (UNII: U705VLF0VW) (COENZYME Q10, (2Z)- - UNII:U705VLF0VW)	COENZYME Q10, (2Z)-	50 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69176-600-30	30 in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		10/16/2017	

### Supplement Facts

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

Amount Per Serving	% Daily Value
color	
shape	
imprint	

size (solid drugs)	18 mm
scoring	1

**Labeler** - TMIG Inc. (036572986)

Revised: 10/2017

TMIG Inc.