#### ONEVITE- onevite tablet NEOMED PHARMACEUTICAL

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Multivitamin and Mineral Supplement Rx only

Each Tablet Contains:

VITAMIN C (AS ASCORBIC ACID)	125 MG
VITAMIN DB (ASCHOLECALCIFEROL)	10 MCG
VITAMIN B1 (ASTHAMINE HCL)	1.5 MG
VITAMIN B2 (AS REOFLAMN)	1.7 MG
(VITAMIN B3) (ASNIACINAMIDE)	20 MG
VITAMIN 86 (AS PYRIDOXINE)	12.5 MG
FOLICACID	1000 MCG
VITAMIN B12 (ASCYANOCOBALAMIN)	1000 MCG
BOTIN	300 MCG
PANTOTHENIC ACID (AS CALCIUM PANTOTHENATE)	10 MG
VITAMINA (ASACETATE)	1500 MCG
VANADIUM (AS VANADYL SULFATE)	200MCG
	100MG
LUTEN	1 MG

**Other Ingredients :** Di calcium phosphate, microcrystalline cellulose, croscarmellose sodium, stearic acid, silicon dioxide, titanium dioxide, PEG 8000, magnesium stearate, talc, HPMC E15 & HPMC E5/E6

#### INDICATIONS AND USAGE

**ONEvite Tablets** is an orally administered prescription vitamin supplement specifically formulated for the clinical dietary management of patients with unique nutritional needs requiring, increased folate levels and nutritional supplementation in physiologically stressful conditions. As well as for maintenance of good health and beneficial in maintaining overall skin health, also help maintain healthy blood sugar levels and help promote nerve health and function including normal vision.

#### CONTRAINDICATIONS

**ONEvite Tablets** is contraindicated in patients with hypersensitivity to any of its components. Folic Acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (Vitamin B12).

#### WARNING/PRECAUTIONS

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur.

Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency.

Avoid Over dosage. Keep out of the reach of children.

### **Drug Interactions**

High doses of folic acid may result in decreased serum levels of anticonvulsant drugs.

Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.

Consult appropriate references for additional specific vitamin-drug interactions.

### **Information for Patients**

Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breastfeeding.

### Pediatric Use

Not recommended for pediatric use.

## **ADVERSE REACTIONS**

Adverse reactions have been reported with specific vitamins and minerals, but generally at levels substantially higher than those in **ONEvite Tablets** 

# DOSAGE AND ADMINISTRATION

**ONEvite Tablets** is a white film coating with caplet shape.

One tablet daily or as directed by a physician.

# HOW SUPPLIED

**ONEvite Tablets** available 90 tablets per bottle,

# 70898-198-09

Store at room temperature 15°-30°C (59°-86°F). Avoid excessive heat and moisture.

To report a serious adverse event or obtain product information, call 631-524-5758

Manufactured for:

Neomed Pharmaceutical

Brentwood, NY 11717

www.neomedpharmaceutical.com

MADE IN USA

DISCLAIMER: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. <u>For further information about unapproved drugs, click here.</u>

#### 70898-198-09

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EACH TABLET CONTAINS: Serving Size: One (1) Tablet		
VITAMIN C (AS ASCORBIC ACID)	125	MG
VITAMIN D3 (AS CHOLECALCIFEROL)	10	MCG
VITAMIN B1 (AS THIAMINE HCL)	1.5	MG
VITAMIN B2 (AS RIBOFLAVIN)	1.7	MG
(VITAMIN B3) (AS NIACINAMIDE)	20	MG
VITAMIN B6 (AS PYRIDOXINE)	12.5	MG
FOLIC ACID	1000	MCG
VITAMIN B12 (AS CYANOCOBALAMIN)	1000	MCG
BIOTIN	300	MCG
PANTOTHENIC ACID (AS CALCIUM PANTOTHENATE)	10	MG
VITAMIN A (AS ACETATE)	1500	MCG
VANADIUM (AS VANADYL SULFATE)	200	MCG
ALPHA LIPOIC ACID	100	MG
LUTEIN	1	MG

Other Ingredients: Di Calcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Silicon Dioxide, Titanium Dioxide, PEG 8000, Magnesium Stearate, Talc, HPMC E15 & HPMC E5/E6 SUGGESTED USE: Take one tablet daily with food or as directed by a physician. Keep bottle tightly closed. Store in cool dry place.

One Vite Tablets are free of Gluten, Sodium, Sugar and Artificial Flavors.

WARNING: If you are pregnant nursing or taking medication, consult your doctor before use.

Keep out of reach of children.

DO NOT USE IF SEAL UNDER CAP IS BROKEN.

Store at room temperature 15°-30°C (59°-86°F). Avoid excessive heat and moisture.

This statement has not been evaluated by the Food and Drug Administration. this product is not intended to diagnose, treat, cure or prevent any disease.

#### Manufactured for

Neomed Pharmaceutical, Brentwood, NY 11717 www.neomedpharmaceutical.com Lot No: Exp Date:

REV 6/19

ONEVITE					
onevite tablet					
Product Information					
Product Type	DIETARY SUPPLEMENT	Item Code (So	urce)	NHRIC:7089	8-198
Route of Administration	ORAL				
Active Ingredient/Active I	Aoiety				
	Ingredient Name		Basis of	Strength	Strengtl
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)			ASCORBIC A	CID	125 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)			CHOLECALCIFEROL		10 ug
THIAMINE HYDRO CHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)			THIAMINE HYDROCHLORIDE		1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)			RIBOFLAVIN		1.7 mg
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)			NIACINAMIDE		20 mg
<b>PYRIDO XINE</b> (UNII: KV2JZ1BI6Z) (PYRIDO XINE - UNII:KV2JZ1BI6Z)			PYRIDO XINE		12.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII: 935E97BOY8)			FOLIC ACID		1000 ug
CYANOCOBALAMIN (UNII: P6 YC	3EG204) (CYANOCOBALAMIN - U	NII:P6 YC3EG204)	CYANOCOBA	ALAMIN	1000 ug
BIOTIN (UNII: 6SO6U10H04) (BIC	TIN - UNII:6SO6U10H04)		BIOTIN		300 ug
CALCIUM PANTOTHENATE (UN UNII:19F5HK2737)	II: 568ET80C3D) (PANTOTHENIC A	CID -	PANTOTHEN	ic acid	10 mg
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)		VITAMIN A		1500 ug	
VANADYL SULFATE (UNII: 6 DU9	Y533FA) (VANADIUM - UNII:00J9J9	XKDE)	VANADYL SU	JLFATE	200 ug
.ALPHALIPOIC ACID (UNII: 73Y	7P0K73Y) (.ALPHALIPOIC ACID -	UNII:73Y7P0K73Y)	.ALPHALIPOIC ACID		100 mg
LUTEIN (UNII: X72A60C9MT) (LUTEIN - UNII:X72A60C9MT)			LUTEIN		1 mg

Inactive Ingredients			
Ingredient Name	Strength		
CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
STEARIC ACID (UNII: 4ELV7Z65AP)			

SILICO	SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)				
TITANI	TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)				
POLYE	POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)				
MAGNE	SIUM STEARATE (	UNII: 70097M6I30)			
TALC (U	UNII: 7SEV7J4R1U)				
HYPRO	MELLOSES (UNII: 3	3NXW29V3WO)			
Packaging					
	0 0				
#	Item Code	Package Description	Marketing S	tart Date M	arketing End Date
#	<b>Item Code</b> C:70898-198-09	<b>Package Description</b> 1 in 1 PACKAGE	Marketing S	tart Date Ma	arketing End Date
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Supplement Facts			
Serving Size :		Serving per Container :	
	Amount Per Serving	% Daily Value	
color			
scoring	1		
shape			
size (solid drugs)	4 mm		

Labeler - NEOMED PHARMACEUTICAL (048388130)

Revised: 6/2019

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