OMNIVEX- omnivex tablet
Sterling Knight Pharmaceuticals LLC

Omnivex Tablets

HEALTH CLAIM:

Omnivex Tablets Dietary Supplement

Dispensed by Prescription†

Supplement Facts

Serving Size: 1 Tablet Servings per Bottle: 30		
Amount Per Serving:	**% Daily Value**	
Vitamin C (as ascorbic acid)	125 mg	208%
Vitamin D3 (as cholecalciferol)	500 IU	125%
Vitamin B1 (as Thiamin HCl)	25 mg	1,667%
Vitamin B6 (as pyridoxal phosphate anhydrous)	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	*
**Daily Values (DV) not established.*		

OTHER INGREDIENTS: Microcrystalline Cellulose, Pregelatinized Corn Starch, Coating (Beta-Carotene, Titanium Dioxide, Hypromellose, Polyvinyl Alcohol, Polyethylene Glycol, talc), Croscarmellose Sodium, Silica, Silicon Dioxide, Hydroxypropyl Cellulose, Magnesium Stearate..

DESCRIPTION:

Omnivex 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.

Omnivex should be administered under the supervision of a licensed medical practitioner.

WARNING AND PRECAUTIONS

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

Omnivex 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.

DOSAGE & ADMINISTRATION

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

INDICATIONS AND USAGE

Omnivex 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.

HOW SUPPLIED HEALTH CLAIM:

Omnivex is supplied as a clear coated oblong tablet dispensed in HDPE plastic bottles of 30ct.

Dispensed by Prescription†

Reserved for Professional Recommendation

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

† 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).1-3 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)

Manufactured for:

Sterling-Knight Pharmaceuticals, LLC

Ripley, MS 38663

Item 36030

Rev. 0418-2

STORAGE AND HANDLING:

Store at controlled room temperature 15°-30°C (59°F-86°F). Keep in cool dry place. Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

KEEP THIS OUT OF THE REACH OF CHILDREN.

PACKAGE LABEL:

OMNIVEX

omnivex tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:69336-360
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	500 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	25 mg
PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	12.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
NADH (UNII: 4J24DQ0916) (NADH - UNII:4J24DQ0916)	NADH	5 mg
COENZYME Q10, (2Z)- (UNII: U705VLF0VW) (COENZYME Q10, (2Z)- - UNII:U705VLF0VW)	COENZYME Q10, (2Z)-	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL 200 (UNII: R95B8J264J)	
TALC (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69336-360-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/16/2018	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
size (solid drugs)	19 mm	
scoring	1	

Labeler - Sterling Knight Pharmaceuticals LLC (079556942)

Revised: 4/2018 Sterling Knight Pharmaceuticals LLC