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

Xyzbac

HEALTH CLAIM

Xyzbac 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%
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	*
*Daily Values (DV) not established.		

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

DESCRIPTION:

Xyzbac 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.

Xyzbac 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

Xyzbac 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:

Xyzbac tablets are supplied as tan, oblong shaped tablets with imprint "314" in a child-resistant bottle of 30ct. (69597-314-30*)

Dispensed by Prescription[†]

*Basiem 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).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)

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.

To report adverse side effects or to obtain product information, contact Basiem, LLC at 1-844-551-9911

PACKAGE LABEL



XYZBAC

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

Product Information						
Product Type	DIETARY SUPPLEMENT	Item Code (Source) NHRIC:69597-314		97-314		
Route of Administration	ORAL					
Active Ingredient/Active Moiety						
Ingra	edient Name		Basis of S	trength	Strength	
ASCORBIC ACID (UNII: PQ6CK8PD	0R) (ASCORBIC ACID - UNII:PC	(6CK8PD0R)	ASCORBIC ACI	D	125 mg	
cholecalciferol (UNII: 1C6V77QF4	1) (CHOLECALCIFEROL - UNII:	1C6V77QF41)	cholecalciferol		500 [iU]	
THIAMINE HYDROCHLORIDE (UN UNII:4ABT0J945J)	II: M572600E5P) (THIAMINE IO	N -	THIAMINE HYDROCHLORI	DE	25 mg	
PYRIDOXAL PHOSPHATE ANHYD PHOSPHATE ANHYDROUS - UNII:F06		YRIDOXAL	PYRIDOXAL PH ANHYDROUS	OSPHATE	12.5 mg	
FOLIC ACID (UNII: 935E97BOY8) (F	OLIC ACID - UNII:935E97BOY	8)	FOLIC ACID		1 mg	
METHYLCOBALAMIN (UNII: BR1S) UNII:BR1SN1JS2W)	11JS2W) (METHYLCOBALAMIN	-	METHYLCOBAL	_AMIN	1 mg	
NADH (UNII: 4J24DQ0916) (NADH -	UNII:4J24DQ0916)		NADH		5 mg	
COENZYME Q10, (2Z)- (UNII: U70 UNII:U705VLF0VW)	5VLF0VW) (COENZYME Q10,	(2Z)	COENZYME Q	10, (2Z)-	50 mg	

Inactive Ingredients				
Ingredient Name	Strength			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				

Packaging				
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69597-314-30	30 in 1 BOTTLE		
Marketing Information				
Μ	arketing Info	ormation		
M		Application Number or Mo Citation	nograph Marketing Date	Start Marketing End Date

Supplement Facts				
Serving Size :		Serving per Container :		
Am	nount Per Serving	% Daily Value		
color				
shape				
imprint				
size (solid drugs)	19 mm			
scoring	1			

Labeler - Basiem (079686680)

Revised: 10/2023

Basiem