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)

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Basiem