

XYZMUNE- ascorbic acid, cholecalciferol, folic acid, zinc, echinacea, l-lysine hcl, tumeric, ginger capsule
Basiem, LLC

XYZMUNE

HEALTH CLAIM:

XYZMUNE Capsules - Dietary Supplement

Dispensed by Prescription‡

Supplement Facts		
Serving Size: 1 Capsule Servings per container: 30		
Amount Per Serving		% Daily Value
Vitamin C (as ascorbic acid)	500 mg	556%
Vitamin D (from cholecalciferol)	15 mcg	75%
Folate (from 1000 mcg folic acid)	1667 mcg DFE	417%
Zinc (as zinc oxide)	16 mg	145%
Echinacea purpurea extract (whole plant)	30 mg	*
L-Lysine hydrochloride	10 mg	*
Turmeric (root) extract	10 mg	*
Ginger (root) extract	5 mg	*

* Daily Value not established

OTHER INGREDIENTS: gelatin, calcium stearate, silica, organic mushroom (Pleurotus eryngii), organic turkey tail (Trametes versicolor), organic cordyceps (Cordyceps militaris), organic reishi (Ganoderma lucidum) organic himematsutake (Agaricus blazei), organic lion's mane (Hericium erinaces), organic antrodia (Taiwanofungus camphoratus (Antrodia camphorate)), organic maitake (Grifola frondosa)

DESCRIPTION:

XYZMUNE is an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nutritional status in patients where advanced supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good immune health is needed.†

XYZMUNE is manufactured in accordance with Current Good Manufacturing Practice for foods, using ingredients that have been approved by the U.S. Food and Drug Administration (FDA) as food additives or are “Generally Recognized as Safe” (GRAS) for their intended use.

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

† These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent disease.

WARNING AND PRECAUTIONS

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

KEEP OUT OF REACH OF CHILDREN

PRECAUTION

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B is deficient. Folic acid in doses above 1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. XYZMUNE capsules should only be used under the direction and supervision of a licensed medical practitioner.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may report side effects by calling 1-844-551-9911 or the FDA by calling 1-800-FDA-1088.

DOSAGE & ADMINISTRATION

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

HOW SUPPLIED HEALTH CLAIM:

XYZMUNE Dietary Supplement
Capsules are clear with a yellow powder inside
Bottles contain 30 capsules, 69597-355-30*
Dispensed by Prescription‡

Manufactured in USA for:
Basiem, LLC
Madisonville, LA 70447

Distributed by: Solubiomix, LLC
Rev. 04/2020

* 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.

‡ The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product by prescription. 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:

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

PACKAGE LABEL

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

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

If you are pregnant or nursing, ask a healthcare professional.

Call your licensed medical practitioner about side effects. You may report side effects by calling Solubiomix at 1-844-551-9911 or 1-800-FDA-1088.


KEEP OUT OF REACH OF CHILDREN

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

Manufactured for: Basiem, LLC, Madisonville, LA 70447
Distributed by: Solubiomix, LLC, Madisonville, LA 70447

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Xyzmune Capsules

IMMUNE HEALTH†

Prescription Folic Acid-Containing Dietary Supplement



Dispensed by Prescription

30 Capsules

Supplement Facts

Serving Size: 1 Capsule
Servings per container: 30

Amount Per Serving	% Daily Value	
Vitamin C (as ascorbic acid)	500 mg	556%
Vitamin D (from cholecalciferol)	15 mcg	75%
Folate (from 1000 mcg folic acid)	1667 mcg DFE	417%
Zinc (as zinc oxide)	16 mg	145%
Echinacea purpurea extract (whole plant)	30 mg	*
L-Lysine hydrochloride	10 mg	*
Turmeric (root) extract	10 mg	*
Ginger (root) extract	5 mg	*

* Daily Value not established

OTHER INGREDIENTS: Capsule (gelatin), silica, calcium stearate, organic mushroom blend (organic king trumpet (*Pleurotus eryngii*), organic cordyceps (*Cordyceps militaris*), organic turkey tail (*Trametes versicolor*), organic reishi (*Ganoderma lucidum*), organic himematsutake (*Agaricus blazei*), organic lion's mane (*Hericium erinaceus*), organic maitake (*Grifola frondosa*), organic *Antrrodia camphorate*, grown on organic oats).

XYZMUNE

ascorbic acid, cholecalciferol, folic acid, zinc, echinacea, l-lysine hcl, tumeric, ginger capsule

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69597-355
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	500 mg
cholecalciferol (UNII: 1C6V77QF41) (cholecalciferol - UNII:1C6V77QF41)	cholecalciferol	0.015 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	16 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
ECHINACEA PURPUREA WHOLE (UNII: QI7G114Y98) (ECHINACEA PURPUREA WHOLE - UNII:QI7G114Y98)	ECHINACEA PURPUREA WHOLE	30 mg
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM) (LYSINE - UNII:K3Z4F929H6)	LYSINE	10 mg
TURMERIC (UNII: 856YO1Z64F) (TURMERIC - UNII:856YO1Z64F)	TURMERIC	10 mg
GINGER (UNII: C5529G5JPQ) (GINGER - UNII:C5529G5JPQ)	GINGER	5 mg

Inactive Ingredients	
Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
PLEUROTUS ERYNGII WHOLE (UNII: 2WGH02ZJ1G)	
TRAMETES VERSICOLOR WHOLE (UNII: 2YD82VN5CM)	
CORDYCEPS MILITARIS WHOLE (UNII: J617U5X7NN)	
GANODERMA LUCIDUM WHOLE (UNII: J5P04QW0CF)	
AGARICUS BLAZEI WHOLE (UNII: 11MSQ4JG7G)	
HERICIUM AMERICANUM WHOLE (UNII: UF625TXW2A)	
TAIWANOFUNGUS CAMPHORATUS WHOLE (UNII: 944OR6BL20)	
GRIFOLA FRONDOSA WHOLE (UNII: O238UC53ET)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69597-355-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		04/08/2020	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value
color	
scoring	1
size (solid drugs)	23 mm
shape	

