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

IMUBOLIC

HEALTH CLAIM:

IMUBOLIC 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 ma 556% 75% Vitamin D (from cholecalciferol) 15 mca Folate (from 1000 mcg folic acid) 1667 mcg DFE 417% Zinc (as zinc oxide) 145% 16 mg Echinacea purpurea extract 30 mg (whole plant) L-Lysine hydrochloride 10 ma Turmeric (root) extract 10 ma Ginger (root) extract 5 mg

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

DESCRIPTION:

IMUBOLIC 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.[†]

IMUBOLIC 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.

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

^{*} Daily Value not established

[†] 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. IMUBOLIC 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. IMUBOLIC 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:

IMUBOLIC Dietary Supplement Capsules are clear with a yellow powder inside Bottles contain 30 capsules, 73308-355-30* Dispensed by Prescription[‡]

Manufactured in USA for:

Ayurax, LLC

Fairhope, AL 36532

Distributed by: Solubiomix, LLC

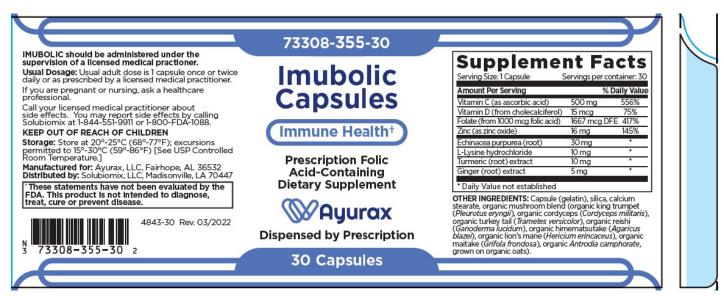
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- * Ayurax does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.
- [‡] 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:



IMUBOLIC

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

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:73308-355
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)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73308-355-30	30 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		03/10/2022	

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

Labeler - Ayurax (117147643)

Revised: 10/2023 Ayurax