

AZALGIA- ascorbic acid, folic acid, calcium, manganese, shark cartilage, glucosamine sulfate, msm, boswella serrata, tumeric extract, chicken cartilage capsule

Basiem, LLC

AZALGIA

HEALTH CLAIM:

AZALGIA Capsules - Dietary Supplement

Dispensed by Prescription‡

Supplement Facts

Serving Size: 2 Capsules
Servings per container: 30

Amount Per Serving		% Daily Value
Vitamin C (as ascorbic acid and sodium ascorbate)	50 mg	56%
Folate (from 1000 mcg folic acid)	1667 mcg DFE	417%
Calcium (from shark cartilage)	35 mg	3%
Manganese (as manganese carbonate)	2.5 mg	109%
Shark cartilage	496 mg	*
Glucosamine Sulfate Potassium Chloride (from shrimp and crab shell)	250 mg	*
Methylsulfonylmethane (MSM)	75 mg	*
Indian frankincense (<i>Boswella serrata</i>) gum extract	25 mg	*
Turmeric Extract	25 mg	*
Chicken cartilage	4 mg	*

* Daily Value not established

OTHER INGREDIENTS: Gelatin, magnesium stearate, maltodextrin

DESCRIPTION:

AZALGIA 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 joint health is needed.†

AZALGIA 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.

‡ AZALGIA 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. AZALGIA 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. AZALGIA 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 2 capsules taken orally once or twice daily or as prescribed by a licensed medical practitioner.

HOW SUPPLIED HEALTH CLAIM:

AZALGIA Dietary Supplement

Capsules are clear with a yellow powder inside

Bottles contain 60 capsules, 69597-354-60*

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:

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

Usual Dosage: Usual adult dose is 2 capsules 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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Rev: 04/2020

69597-354-60

Azalgia Capsules

JOINT HEALTH†

Prescription Folic Acid-Containing Dietary Supplement



Dispensed by Prescription

Supplement Facts

Serving Size: 2 Capsules
Servings per container: 30

Amount Per Serving	% Daily Value
Vitamin C (as ascorbic acid and sodium ascorbate)	50 mg 56%
Folate (from 1000 mcg folic acid)	1667 mcg DFE 417%
Calcium (from shark cartilage)	35 mg 3%
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Shark cartilage	496 mg *
Glucosamine Sulfate Potassium Chloride (from shrimp and crab shell)	250 mg *
Methylsulfonylmethane (MSM)	75 mg *
Indian frankincense (<i>Boswellia serrata</i>) gum extract	25 mg *
Turmeric Extract	25 mg *
Chicken cartilage	4 mg *

* Daily Value not established

OTHER INGREDIENTS: Capsule (gelatin), magnesium stearate (vegetable source), maltodextrin

CONTAINS: Fish and Shellfish



60 Capsules

AZALGIA

ascorbic acid, folic acid, calcium, manganese, shark cartilage, glucosamine sulfate, msm, boswellia serrata, tumeric extract, chicken cartilage capsule

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69597-354
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	25 mg
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	17.5 mg
MANGANESE CARBONATE (UNII: 9ZV57512ZM) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	1.25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.5 mg
SHARK CARTILAGE (UNII: D2YCN1I522) (SHARK CARTILAGE - UNII:D2YCN1I522)	SHARK CARTILAGE	248 mg
GLUCOSAMINE SULFATE (UNII: 1FW7WLR731) (GLUCOSAMINE - UNII:N08U5BOQ1K)	GLUCOSAMINE SULFATE	175 mg
DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) (DIMETHYL SULFONE - UNII:9H4PO4Z4FT)	DIMETHYL SULFONE	37.5 mg
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M) (INDIAN FRANKINCENSE - UNII:4PW41QCO2M)	INDIAN FRANKINCENSE	12.5 mg
TURMERIC (UNII: 856YO1Z64F) (TURMERIC - UNII:856YO1Z64F)	TURMERIC	12.5 mg
CHICKEN CARTILAGE (UNII: FL87LV6WRO) (CHICKEN CARTILAGE - UNII:FL87LV6WRO)	CHICKEN CARTILAGE	2 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	

MALTODEXTRIN (UNII: 7CVR7L4A2D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69597-354-60	60 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)	21 mm	
shape		

Labeler - Basiem, LLC (079686680)

Revised: 4/2020

Basiem, LLC