

**NITRIVIA- niacin, folate, calcium, l-arginine, l-ornithine, beet, gotu kola, carrot, celery extract capsule
Solubiomix, LLC**

NITRIVIA

STATEMENT OF IDENTITY

NITRIVIA Dietary Supplement for Nitric Oxide Health

Dispensed by Prescription[†]

Serving Size: 1 Capsule
Servings per container: 30

	Amount Per Serving: %DV	
Niacin (from no-flush inositol hexanicotinate)	100 mg	625%
Folate (from 1,000 mcg folic acid)	1665 mcg DFE	416%
Calcium (as calcium phosphate)	250 mg	5%
L-Arginine	250 mg	*
L-Ornithine	250 mg	*
Organic Fermented Beet (root)	250 mg	*
Gotu Kola (Centella asiatica whole herb)	40 mg	*
Carrot (root)	40 mg	*
Celery extract (seed)	20 mg	*

*Daily Values (DV) not established

OTHER INGREDIENTS: Capsule (gelatin), calcium stearate, silica.

Gluten Free

NITRIVIA capsules are an orally administered prescription vitamin formulation for the clinical dietary management of suboptimal nitric oxide and nutritional status in patients where advanced folate supplementation is required, and nutritional supplementation in physiologically stressful conditions for maintenance of good health is needed.

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

prevent disease.

NITRIVIA 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.

DOSAGE

Usual adult dose is 2 capsule once or twice daily, or as prescribed by a licensed medical practitioner.

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

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

SAFE HANDLING

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. NITRIVIA Capsules should only be used under the direction and supervision of a licensed medical practitioner.†

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

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.

In case of accidental overdose, call a doctor or poison control center immediately.

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.

STORAGE

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.

Tamper Evident: Do not use if seal is broken or missing.

HOW SUPPLIED HEALTH CLAIM

NITRIVIA, Nitric Oxide Health

Dietary Supplement

Each bottles contains 60 Capsules (white) 69499-354-60#

NITRIVIA Capsules are available as white, oblong capsules without and imprint and are available in 60-count bottles (69499-354-60#).

This product is not an Orange Book product.

Manufactured in USA for:

Solubiomix, LLC

Madisonville, LA 70447

Rev. 07/2023

Solubiomix 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.

†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)

PRINCIPAL DISPLAY PANEL

<p>Distributed by: Solubiomix, LLC Madisonville, LA 70447</p> <p>NITRIVIA should be administered under the supervision of a licensed medical practitioner.</p> <p>Usual Dosage: Usual adult dose is 2 capsules once or twice daily or as prescribed by a licensed practitioner.</p> <p>KEEP OUT OF REACH OF CHILDREN</p> <p>STORAGE: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). Protect from light and moisture.</p> <p>4845-60 Rev. 07/2023</p>  <p>N 3 69499-354-60 6</p>	<p>69499-354-60</p> <h1>NITRIVIA Capsules</h1> <p>Nitric Oxide Health</p> <p>Prescription Folic Acid-Containing Dietary Supplement</p>  <p>Dispensed by Prescription</p> <p>Contents: 60 Capsules</p>	<table border="1"><thead><tr><th colspan="3">Supplement Facts</th></tr><tr><td colspan="3">Serving Size: 2 Capsules Servings per container: 30</td></tr><tr><th>Amount Per Serving:</th><th colspan="2">%Daily Value</th></tr></thead><tbody><tr><td>Niacin (from no-flush inositol hexanicotinate)</td><td>100 mg</td><td>625%</td></tr><tr><td>Folate (from 1,000 mcg folic acid)</td><td>1665 mcg DFE</td><td>416%</td></tr><tr><td>Calcium (as calcium phosphate)</td><td>60 mg</td><td>5%</td></tr><tr><td>L-Arginine</td><td>250 mg</td><td>*</td></tr><tr><td>L-Ornithine</td><td>250 mg</td><td>*</td></tr><tr><td>Organic fermented Beet (root)</td><td>250 mg</td><td>*</td></tr><tr><td>Gotu Kola (whole herb)</td><td>40 mg</td><td>*</td></tr><tr><td>Carrot (root)</td><td>40 mg</td><td>*</td></tr><tr><td>Celery extract (seed)</td><td>20 mg</td><td>*</td></tr></tbody></table> <p>*Daily Values (DV) not established.</p> <p>OTHER INGREDIENTS: Gelatin capsule, cellulose, calcium stearate, silica.</p>	Supplement Facts			Serving Size: 2 Capsules Servings per container: 30			Amount Per Serving:	%Daily Value		Niacin (from no-flush inositol hexanicotinate)	100 mg	625%	Folate (from 1,000 mcg folic acid)	1665 mcg DFE	416%	Calcium (as calcium phosphate)	60 mg	5%	L-Arginine	250 mg	*	L-Ornithine	250 mg	*	Organic fermented Beet (root)	250 mg	*	Gotu Kola (whole herb)	40 mg	*	Carrot (root)	40 mg	*	Celery extract (seed)	20 mg	*
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Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69499-354
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INOSITOL NIACINATE (UNII: A99MK953KZ) (INOSITOL NIACINATE - UNII:A99MK953KZ)	INOSITOL NIACINATE	100 mg
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J) (CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS - UNII:L11K75P92J)	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	60 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
ARGININE (UNII: 94ZLA3W45F) (ARGININE - UNII:94ZLA3W45F)	ARGININE	250 mg
ORNITHINE (UNII: E524N2IXA3) (ORNITHINE - UNII:E524N2IXA3)	ORNITHINE	250 mg
BEET (UNII: N487KM8COK) (BEET - UNII:N487KM8COK)	BEET	250 mg
CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)	CENTELLA ASIATICA	40 mg
CARROT (UNII: L56Z1JK48B) (CARROT - UNII:L56Z1JK48B)	CARROT	40 mg
CELERY SEED (UNII: 1G1EAA320L) (CELERY SEED - UNII:1G1EAA320L)	CELERY SEED	20 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
CALCIUM STEARATE (UNII: 776XM7047L)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
CELLULOSE SULFATE (UNII: VR47YBL2QJ)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69499-354-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		07/06/2023	

Supplement Facts

Serving Size :

Serving per Container :

	Amount Per Serving	% Daily Value
scoring	1	
shape		
size (solid drugs)	22 mm	
color		

Labeler - Solubiomix, LLC (079640556)

Revised: 8/2023

Solubiomix, LLC