

AZESCO- ascorbic acid, cholecalciferol, thiamin, pyridoxal-5-phosphate, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, iodine tablet
Solubiomix

Azesco

HEALTH CLAIM:

Azesco Tablets - Prenatal/Postnatal/Folate Health 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	104%
Vitamin D3 (as cholecalciferol)	12.5 mcg	83%
Thiamin (Vitamin B1 as thiamin HCl)	1.4 mg	100%
Vitamin B6 (as pyridoxal 5' phosphate)	2.5 mg	125%
Folic Acid	1 mg	278%
Vitamin B12 (as methylcobalamin)	1 mg	3,5714%
Calcium (from calcium carbonate)	200 mg	15%
Iron (as ferrous gluconate)	13 mg	48%
Iodine (as potassium iodide)	150 mcg	52%

OTHER INGREDIENTS: cellulose, magnesium stearate, and silicon dioxide.

DESCRIPTION:

Azesco 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.

Azesco Tablets is a prescription dietary supplement for use throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. Azesco Tablets may be useful in improving the nutritional status of women prior to conception.

WARNING AND PRECAUTIONS

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

CONTRAINDICATIONSAzesco Tablets are contraindicated in patients with a known hypersensitivity to any of the ingredients. Do not take this product if you are presently taking mineral oil, unless directed by a doctor.

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. Azesco Tablets 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 tablet taken orally once or twice daily or as prescribed by a licensed medical practitioner.

HOW SUPPLIED HEALTH CLAIM:

Azesco Tablets are available as tan, oblong tablets imprinted "0344" and are available in 30-count bottles (69499-344-30*). This product is not an Orange Book product.

Dispensed by Prescription†

MADE IN USA
Rev. 02/19

*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)

STORAGE AND HANDLING:

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.

Distributed by:
Solubiomix, LLC
Madisonville, LA 70447

PACKAGE LABEL:



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

69499-344-30

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.

Azesco Tablets

Dietary Supplement



Dispensed by Prescription

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.

STORAGE: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30° (59°-86°F) Protect from heat, light and moisture.

Distributed By: Solubiomix, LLC
Madisonville, LA 70447
MADE IN USA OF DOMESTIC AND INTERNATIONAL
INGREDIENTS • Rev. 10/2019

Supplement Facts

Serving Size: 1 Tablet Servings per container: 30

Amount Per Serving:	% Daily Value*	
Vitamin C (as ascorbic acid)	125 mg	104%
Vitamin D (as cholecalciferol)	12.5 mcg (500 IU)	83%
Thiamine (as hydrochloride)	1.4 mg	100%
Vitamin B6 (as pyridoxal-5-phosphate)	2.5 mg	125%
Folate	1,667 DFE (1 mg folic acid)	278%
Vitamin B12 (as methylcobalamin)	1,000 mcg	35,714%
Calcium (from calcium carbonate)	200 mg	15%
Iron (as ferrous gluconate)	13 mg	48%
Iodine (as potassium iodide)	150 mcg	52%

* % Daily Value for pregnant and lactating women

Other Ingredients: Microcrystalline cellulose, magnesium stearate, silica, glycerin, vanilla extract.

30 Tablets

AZESCO

ascorbic acid, cholecalciferol, thiamin, pyridoxal-5-phosphate, folic acid, methylcobalamin, calcium carbonate, ferrous gluconate, iodine tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRC:69499-344
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
cholecalciferol (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	cholecalciferol	0.0125 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.4 mg
PYRIDOXAL PHOSPHATE ANHYDROUS (UNII: F06SGE49M6) (PYRIDOXAL PHOSPHATE ANHYDROUS - UNII:F06SGE49M6)	PYRIDOXAL PHOSPHATE ANHYDROUS	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	1 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS GLUCONATE (UNII: U1B11423Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	13 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	.15 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:69499-344-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		02/01/2019	

Supplement Facts**Serving Size :** **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
shape		
imprint		
size (solid drugs)	19 mm	
scoring	1	

Labeler - Solubiomix (079640556)

Revised: 11/2019

Solubiomix