

AZESCHEW- ascorbic acid, cholecalciferol, thiamin, pyridoxine hydrochloride, folic acid, methylcobalamin, calcium citrate, ferrous fumarate, iodine bar, chewable
Basiem, LLC

AzesChew Chews

HEALTH CLAIM:

AzesChew Chews - Prenatal/Postnatal/Folate Health Dietary Supplement

Dispensed by Prescription†

Supplement Facts

Serving Size 1 Chew Servings per container 30

Amount Per Serving % Daily Value		
Calories	20	
Total Fat	0.5 g	1%*
Saturated Fat	0 g	0%*
Total Carbohydrates	4 g	1%*
Total Sugars	2 g	**
Includes 2g Added Sugars		4%*
Vitamin C (as ascorbic acid)	125 g	139%
Vitamin D (as cholecalciferol)	12.5 mcg	63%
Thiamin (as thiamin mononitrate)	1.4 mg	117%
Vitamin B ₆ (as pyridoxine HCl)	2.5 mg	147%
Folate	1886 mcg DFE (1000 mcg folic acid)	41667%
Vitamin B ₁₂ (as methylcobalamin)	1000 mcg	1667%
Calcium (as calcium citrate)	200 mg	15%
Iron (as ferrous fumarate)	13 mg	72%
Iodine (as potassium iodine)	150 mcg	100%
Sodium	150 mcg	100%

*Percent Daily Values are based on a 2,000 calorie diet.

**Daily Value not established.

OTHER INGREDIENTS: Tapioca Syrup, Raw Cane Sugar, Palm Oil, Fruit and Vegetable Juice (Color), Natural Flavor, Sunflower Lecithin, Citric Acid, Sea Salt.

DESCRIPTION:

AZESCHEW 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.

AZESCHEW 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. AZESCHEW chews may be useful in improving the nutritional status of women prior to conception.

AZESCHEW 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. AZESCHEW 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.

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.

CONTRAINDICATIONS AZESCHEW chews 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. AZESCHEW chews 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 chew taken orally once or twice daily or as prescribed by a licensed medical practitioner.

DIRECTIONS FOR USE: REMOVE FOIL BEFORE CONSUMING CHEW. Consume entire chew or as directed by a healthcare professional.

HOW SUPPLIED HEALTH CLAIM:

AZESCHEW, Prenatal/Postnatal Support Dietary Supplement.

Chews are beige in color and individually wrapped in a strawberry colored foil. Each bottles contain 30 Chews 69597-353-30†

Dispensed by Prescription‡

Manufactured in United States for:

Basim, LLC

Madisonville, LA 70447

Dispensed by Prescription†

MADE IN USA

Rev. 01/20

† 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 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 in a cool, dry place.

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

Distributed by:
Solubiomix, LLC
Madisonville, LA 70447

PACKAGE LABEL:

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

69597-353-30

AzesChew
PRENATAL/POSTNATAL

Prescription Folic Acid-Containing Dietary Supplement

Strawberry Flavor

BASIEM
Baseline Solutions for Iron Errors of Metabolism

Dispensed by Prescription

30 Chews

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Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:69597-353
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	12.5 mg
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.4 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE -	PYRIDOXINE	2.5 mg

