

AZENTRA- ascorbic acid, cholecalciferol, thiamine, pyridoxal hcl, folic acid, methylcobalamin, riboflavin, niacinamide, calcium carbonate, ferrous gluconate, iodine tablet
Blue Heron Pharmaceuticals, LLC

AzentraPrenatal/Postnatal Tablets

Health Claim:

Azentra

Prenatal/Postnatal Tablets

Dispensed by Prescription

SUPPLEMENT FACTS		
Serving Size: 1 tablet		
Servings Per Container: 30		
Amt. Per Serving:	%DV	‡
<i>Vitamin B1 (as Thiamine Mononitrate)</i>	1.4 mg	117%
<i>Vitamin B2 (as Riboflavin)</i>	2.5 mg	192%
<i>Vitamin B3 (as Niacinamide)</i>	16 mg	100%
<i>Vitamin B6 (as Pyridoxine HCL)</i>	2.5 mg	147%
<i>Vitamin B12 (As Methylcobalamin)</i>	4.8 mcg	200%
<i>Vitamin C (as Ascorbic Acid)</i>	125 mg	139%
<i>Vitamin D3 (as Cholecalciferol)</i>	12.5 mcg (500 IU)	63%
<i>Folate (as Folic Acid 1,000 mcg)</i>	1,667 mcg DFE	417%
<i>Calcium (as Calcium Carbonate)</i>	200 mg	15%
<i>Iodine (as Potassium Iodide)</i>	150 mcg	100%
<i>Iron (as Ferrous Gluconate)</i>	13 mg	72%
‡ % Daily value not established		

Other ingredients: Microcrystalline Cellulose, Silicon Dioxide, Magnesium Stearate, Stearic Acid, Croscarmellose Sodium.

Description:

Azentra Tablets are white, oval tablets in plastic bottles of 30 ct.

85622-0204-30

Reserved for Professional Recommendation

Azentra 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.

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

This listed product is not a National Drug Code, but instead has merely been formatted to comply with standard industry practice for pharmacy and insurance computer systems.

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

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product. This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:

Blue Heron Pharmaceuticals

Lutz, FL 33559

Warnings:

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.

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

Azentra Tablets 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.

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

Dosage:

Usual adult dose is 1 tablet taken orally once or twice daily or as prescribed by a licensed medical practitioner.

Storage:

CONTRAINDICATIONS

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

PRECAUTIONS

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

ADVERSE REACTIONS

Allergic sensitizations have been reported following oral administration of folic acid. Consult your physician immediately if adverse side effects occur.

KEEP OUT OF THE REACH OF CHILDREN.

Label:

Store at 20° to 25°C (68° to 77°F; excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Label:

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Lot:
EXP:



85622-0204-30



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Manufactured for:
Blue Heron Pharmaceuticals
2831 Allegra Way Suite 218 Lutz FL 33559
Questions? Call: 813-380-0271
www.blueheronpharma.com

85622-0204-30

AZENTRA

ascorbic acid, cholecalciferol, thiamine, pyridoxal hcl, folic acid, methylcobalamin, riboflavin, niacinamide, calcium carbonate, ferrous gluconate, iodine tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:85622-204
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of	Strength
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Ingredient Name	Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	125 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	12.5 ug
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.4 mg
PYRIDOXINE HCL (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	2.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	4.8 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
FERROUS GLUCONATE (UNII: U1B11I423Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	13 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	2.5 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	16 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:85622-204-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		05/13/2026	

Supplement Facts

Serving Size : **Serving per Container :**

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

Labeler - Blue Heron Pharmaceuticals, LLC (137019051)

