

PRENOVA- beta carotene, thiamine, riboflavin, niacinamide, pyridoxine hcl, cyanocobalamin, ascorbic acid, dl-alpha tocopheryl acetate, folic acid, calcium carbonate, ferrous fumarate, zinc oxide tablet
Blue Heron Pharmaceuticals, LLC

Prenova
Prenatal Tablets

Health Claim:

Prenova

Prenatal

Dispensed by Prescription

SUPPLEMENT FACTS		
Serving Size: 1 tablet		
Servings Per Container: 30		
Amt. Per Serving:	%DV ‡	
<i>Vitamin A (as Beta Carotene)</i>	<i>1200 mcg</i>	<i>92%</i>
<i>Vitamin B1 (as Thiamine Mononitrate)</i>	<i>1.8 mg</i>	<i>129%</i>
<i>Vitamin B2 (as Riboflavin)</i>	<i>1.7 mg</i>	<i>106%</i>
<i>Vitamin B3 (as Niacinamide)</i>	<i>20 mg</i>	<i>125%</i>
<i>Vitamin B6 (as Pyridoxine HCL)</i>	<i>2.6 mg</i>	<i>130%</i>
<i>Vitamin B12 (As Cyanocobalamin)</i>	<i>8 mcg</i>	<i>286%</i>
<i>Vitamin C (as Ascorbic Acid)</i>	<i>120 mg</i>	<i>100%</i>
<i>Vitamin D3 (as Cholecalciferol)</i>	<i>10 mcg (400 IU)</i>	<i>67%</i>
<i>Vitamin E (dl-alpha Tocopheryl Acetate)</i>	<i>13.5 mg</i>	<i>71%</i>
<i>Folate (as Folic Acid 800 mcg)</i>	<i>1333 mcg DFE</i>	<i>333%</i>
<i>Calcium (as Calcium Carbonate)</i>	<i>244 mg</i>	<i>19%</i>
<i>Iron (as Ferrous Fumarate)</i>	<i>28 mg</i>	<i>104%</i>
<i>Zinc (as Zinc Oxide)</i>	<i>25 mg</i>	<i>192%</i>
***% Daily value not established		

Inactive Ingredients: Microcrystalline Cellulose, Stearic Acid, Hydroxypropyl Methylcellulose, Croscarmellose Sodium, Silicon Dioxide, Vegetable Magnesium Stearate, Glyceryl Triacetate, Titanium Dioxide, FD&C Red #40, FD&C Yellow #6, <1% Tocopherols, Maltodextrin, Alginate, Gum Acacia, Pea Starch and Sucrose as processing aids.

Description:

Prenova Tablets are pink, oval tablets in plastic bottles of 30 ct.

85622-0202-30

Reserved for Professional Recommendation

Prenova 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.

Prenova 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.

Prenova 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 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:

Dosage: Usual adult dose is one tablet once to twice daily, or as prescribed by a licensed medical practitioner.

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

KEEP OUT OF THE REACH OF CHILDREN.

Warning: Accidental overdoses of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdoses, call a doctor or poison control center immediately. Poison Control Center: 1-800-222-1222

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

Lot:
EXP:



85622-0202-30



30 TABLETS
DIETARY SUPPLEMENT

SUPPLEMENT FACTS

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Servings Per Container: 30

Amt. Per Serving:		%DV ‡
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STORAGE: 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.] Protect from light and moisture.

Manufactured for:
Blue Heron Pharmaceuticals
2831 Allegra Way Suite 218 Lutz FL 33559
Questions? Call: 813-880-0271
www.blueheronpharma.com

85622-0202-30

PRENOVA

beta carotene, thiamine, riboflavin, niacinamide, pyridoxine hcl, cyanocobalamin, ascorbic acid, dl-alpha tocopheryl acetate, folic acid, calcium carbonate, ferrous fumarate, zinc oxide tablet

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:85622-202
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	1200 ug
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.8 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.7 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HCL (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	2.6 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	8 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	13.5 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	800 ug
CALCIUM (UNII: SY7Q814VUP) (CALCIUM - UNII:SY7Q814VUP)	CALCIUM	244 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	28 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:85622-202-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
dietary supplement		05/20/2026	

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)