

**NATALCHEW- .beta.-carotene, ascorbic acid, sodium ascorbate, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and ferrous fumarate tablet**  
**Blue Heron Pharmaceuticals, LLC**

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**NatalChew Chewable**

**Health Claim Section:**

NatalChew Tablets

Dispensed by Prescription

<b>SUPPLEMENT FACTS</b>		
Serving Size: 1 tablet		
Servings Per Container: 30		
<b>Amt. Per Serving:</b>		<b>%DV ‡</b>
<i>Vitamin A (as Beta-Carotene)</i>	300 mcg RAE (1000 IU)	33%
<i>Vitamin B1 (as Thiamine Mononitrate)</i>	2 mg	167%
<i>Vitamin B2 (as Riboflavin)</i>	3 mg	231%
<i>Vitamin B3 (as Niacinamide)</i>	20 mg	125%
<i>Vitamin B6 (as Pyridoxine HCL)</i>	10 mg	588%
<i>Vitamin B12 (As Cyanocobalamin)</i>	12 mcg	500%
<i>Vitamin C (as Ascorbic Acid)</i>	120 mg	133%
<i>Vitamin D3 (as Cholecalciferol)</i>	10 mcg (400 IU)	50%
<i>Vitamin E (dl-alpha Tocopherol Acetate)</i>	11 mg	73%
<i>Folate (as Folic Acid 1,000 mcg)</i>	1,667 mcg DFE	417%
<i>Iron (as Ferrous Fumarate)</i>	29 mg	161%
***% Daily value not established		

**Inactive Ingredients:** Isomalt, Citric Acid, Stearic Acid, Magnesium Stearate, Natural Orange Flavor, Sucralose

**Description:**

NatalChew Tablets are orange-flavored, chewable tablets in plastic bottles of 30 ct.

85622-0203-30

Reserved for Professional Recommendation

NatalChew Tablets are an orally administered prescription vitamin to provide significant amounts of Vitamins A, B6, B12, C, D3, E, riboflavin, niacinamide, thiamine mononitrate, folate and iron to supplement the diet, and to help assure that nutritional deficiencies of

these vitamins will not develop.

NatalChew 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 PRODUCT OUT OF 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.

NatalChew 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.

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### **Precautions:**

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B<sub>12</sub> is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive.

### **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.

### Dosage:

Usual adult dose is 1 chewable tablet by mouth once daily, or as prescribed by a licensed medical practitioner.

### 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 moisture and excessive heat. Note that contact with moisture may produce surface discoloration of the tablet.

### Label:

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NatalChew 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.

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Lot: .....  
EXP: .....



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Inactive Ingredients: Isomalt, Citric Acid, Stearic Acid, Magnesium Stearate, Natural Orange Flavor, Sucralose

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: 813-380-0271 www.blueheronpharma.com

85622-0203-30

## NATALCHEW

.beta.-carotene, ascorbic acid, sodium ascorbate, cholecalciferol, .alpha.-tocopherol acetate, dl-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, and ferrous fumarate tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:85622-203
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BETA CAROTENE</b> (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	1000 [iU]
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
<b>cholecalciferol</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	cholecalciferol	10 mg
<b>.alpha.-tocopherol acetate, dl-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	11 mg
<b>thiamine mononitrate</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	2 mg
<b>riboflavin</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	riboflavin	3 mg
<b>niacinamide</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	niacinamide	20 mg
<b>pyridoxine Hydrochloride</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	pyridoxine Hydrochloride	10 mg
<b>folic acid</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	folic acid	1 mg
<b>cyanocobalamin</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	cyanocobalamin	12 ug
<b>ferrous fumarate</b> (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	29 mg

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:85622-203-30	30 in 1 BOTTLE, PLASTIC		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		03/06/2026	

**Supplement Facts**

**Serving Size :** **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
flavor		
scoring	1	
shape		
size (solid drugs)	12 mm	

**Labeler -** Blue Heron Pharmaceuticals, LLC (137019051)