

PRENATE CHEWABLE- calcium carbonate, cholecalciferol, magnesium oxide, boron, folic acid, pyridoxine hydrochloride, cyanocobalamin, biotin and bilberry tablet, chewable
Avion Pharmaceuticals, LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Prenate chewable ®

A chewable Rx prenatal vitamin with a delicious chocolate flavor

Rx Only

DESCRIPTION: PRENATE CHEWABLE ® is a prescription prenatal/postnatal multivitamin/mineral chocolate chewable tablet. Each tablet is brown and imprinted with "Prenate Chew" on one side and blank on the other.

Supplement Facts

Serving Size: 1 Tablet

Amount per Serving:	% Daily Value
Calcium (as calcium carbonate)	500 mg
Vitamin D3	300 IU
Magnesium (as magnesium oxide)	50 mg
Boron Amino Acid Chelate	250 mcg
Folate 1.1 mg Quatrefolic® ((6S)-5-methyltetrahydrofolate glucosamine salt equivalent to 600 mcg of folic acid and folic acid, USP 400 mcg)	1mg
Vitamin B6 (as pyridoxine HCL)	10 mg
Vitamin B12 (as Cyanocobalamin)	125 mcg
Biotin	280 mcg
Blueberry Extract	25 mg

OTHER INGREDIENTS: Chocolate Flavor, Gum Acacia, Fructose, Magnesium Stearate, Natural Dutch Chocolate, Silicone Dioxide and Silica (as Sipernat ®), and Hydrogenated Vegetable Oil (as Sterotex ®).

INDICATIONS: PRENATE CHEWABLE ® is a multivitamin/multimineral dietary supplement indicated for use in improving the nutritional status of women throughout pregnancy and in the postnatal period for both lactating and nonlactating mothers. PRENATE CHEWABLE ™ can also be beneficial in improving the nutritional status of women prior to conception.

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PRECAUTIONS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

ADVERSE REACTIONS: Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DOSAGE AND ADMINISTRATION: One tablet daily or as directed by a physician.

HOW SUPPLIED: PRENATE CHEWABLE[®] is supplied in child-resistant bottles of 30 tablets (75854-306-30).

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

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

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.

MANUFACTURED FOR: Avion Pharmaceuticals, LLC

Atlanta, GA 30350

1-888-61-AVION

*Quatrefolic[®] is a registered trademark of Gnosis, SpA. Covered by one or more claims of U.S. Patent # 7,947,662 CAS# 1181972-37-1

Rev. 0619-05

75854-306-30

Prenate chewable[®]

**A chewable Rx prenatal vitamin with a delicious chocolate flavor
with Quatrefolic[®]**

Dietary Supplement

30 Tablets

Rx Only

**Avion
PHARMACEUTICALS**

DESCRIPTION: PRENATE CHEWABLE® is a prescription prenatal/postnatal multivitamin/mineral chocolate chewable tablet. Each tablet is brown and imprinted with "Prenate Chew" on one side and blank on the other.

Supplement Facts			
Serving Size: 1 Tablet		% Daily Value	% Daily Value (Pregnant & Lactating Women)
Each Capsule Contains:			
Calcium (as calcium carbonate)	500 mg	50%	38%
Vitamin D3	300 IU	75%	75%
Magnesium (as magnesium oxide)	50 mg	13%	11%
Folate	1 mg	250%	125%
1.1 mg Quatrefolic® ((6S)-5-methyltetrahydrofolate glucosamine salt equivalent to 600 mcg of folic acid and folic acid, USP 400 mcg)			
Vitamin B6 (as pyridoxine HCl)	10 mg	500%	400%
Vitamin B12 (as cyanocobalamin)	125 mcg	2083%	1563%
Biotin	280 mcg	93%	93%
Boron Amino Acid Chelate	250 mcg	†	†
Blueberry extract	25 mg	†	†

† Daily Value (DV) not established.
OTHER INGREDIENTS: Chocolate Flavor, Gum Acacia, Fructose, Magnesium Stearate, Natural Dutch Chocolate, Silicone Dioxide and Silica (as Sipernat®), and Hydrogenated Vegetable Oil (as Sterotex®).

75854-306-30

Prenate chewable®
A chewable Rx prenatal vitamin with a delicious chocolate flavor



With **Quatrefolic®**
Dietary Supplement

30 Tablets
 Rx Only

Avion
 PHARMACEUTICALS

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 *Quatrefolic® is a registered trademark of Gnosis, SpA. Covered by one or more claims of U.S. Patent # 7,947,662 CAS# 1181972-37-1.

PRECAUTIONS: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient. Folic acid in doses above 1.0 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. While prescribing this nutritional supplement for pregnant women, nursing mothers or for women prior to conception, their medical condition and other drugs, herbs and/or supplements consumption should be considered.

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KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Distributed By:
 Avion Pharmaceuticals, LLC
 Alpharetta, GA 30005
 1-866-61-AVION Rev 0219-05



PRENATE CHEWABLE

calcium carbonate, cholecalciferol, magnesium oxide, boron, folic acid, pyridoxine hydrochloride, cyanocobalamin, biotin and bilberry tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75854-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6Z B)	CALCIUM CATION	500 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	300 [iU]
MAGNESIUM OXIDE (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	50 mg
BORON (UNII: N9E3X5056Q) (BORON - UNII:N9E3X5056Q)	BORON	250 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	10 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	125 mg
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	280 ug
BILBERRY (UNII: 9P2U39H18W) (BILBERRY - UNII:9P2U39H18W)	BILBERRY	25 mg

Inactive Ingredients

Ingredient Name	Strength
FRUCTOSE (UNII: 6YSS42VSEV)	
ACACIA (UNII: 5C5403N26O)	
MAGNESIUM STEARATE (UNII: 70097M613O)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

Product Characteristics

Color	brown	Score	2 pieces
Shape	ROUND	Size	22mm
Flavor	CHOCOLATE	Imprint Code	PrenateChew
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-306-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/16/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/16/2013	

Labeler - Avion Pharmaceuticals, LLC (040348516)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-306)

Revised: 1/2024

Avion Pharmaceuticals, LLC