

**PRENATE AM- .pyridoxine hydrochloride, cyanocobalamin, calcium carbonate and folic acid tablet, coated**

**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.*

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**PRENATE AM<sup>®</sup>**

**Dietary Supplement**

**Rx prenatal vitamin with B vitamins and Ginger**

**With**

**Quatrefolic<sup>®</sup>**

**Rx Only**

**DESCRIPTION:** PRENATE<sup>®</sup> AM is a yellow, oval, oil- and water-soluble, multivitamin/multimineral, film-coated tablet debossed with "Prenate" on one side and "AM" on the other.

<b>Supplement Facts</b>	
Serving Size: 1 Tablet	
<b>Each Tablet Contains :</b>	
Vitamin B6 (Pyridoxine Hydrochloride)	75 mg
Vitamin B12 (Cyanocobalamin)	12 mcg
Calcium (as Calcium Carbonate)	200 mg
Folate (as 1.1 mg Quatrefolic <sup>®</sup> ((6S)-5, methyltetrahydrofolate glucosamine salt* CAS 1181972-37-1) molar equivalent to 600 mcg of Folic Acid) (folic acid, USP 400 mcg)	1 mg
Ginger Extract	500 mg
Lingonberry	25 mg

**OTHER INGREDIENTS:** Methocel K, stearic acid, magnesium stearate and silicon dioxide, dicalcium phosphate

**PRECAUTIONS:** Concomitant use of ginger in patients with bleeding disorders, or who are on anti-coagulant or anti-platelet therapy, may increase the risk of bleeding. 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. While prescribing this nutritional supplement for pregnant women, nursing mothers or for women prior to conception, their medical condition and any drugs, herbs and/or supplements consumption should be considered.

**DOSAGE AND ADMINISTRATION:** One tablet daily or as directed by your doctor.

**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.**

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

Room Temperature.]

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

**DISTRIBUTED BY:**

Avion Pharmaceuticals, LLC  
Atlanta, GA 30350 1-888-61-AVION Rev. 0513

The listed product number is not a National Drug Code. Instead, Avion Pharmaceuticals has assigned a product code formatted according to standard industry practice to meet the formatting requirements of pharmacy and healthcare insurance computer systems.

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

PRENATE<sup>®</sup> AM is a registered trademark of Acella Pharmaceuticals, LLC. Under license from Acella Pharmaceuticals, LLC. All rights reserved.

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

75854-307-30

**Prenate<sup>®</sup> Am**  
**Dietary Supplement**  
**Rx prenatal vitamin with B vitamins and Ginger**  
**With**  
**Quatrefolic<sup>®</sup>**

PRENATE<sup>®</sup> AM's formulation eases symptoms commonly associated with pregnancy, including nausea and vomiting.

**30 Tablets**

Rx Only

**Avion**  
**PHARMACEUTICALS**

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Atlanta, GA 30350  
1-888-61-AVION Rev 0513

Lot: \_\_\_\_\_ Exp: \_\_\_\_\_

75854-307-30

**PRENATE AM**

.pyridoxine hydrochloride, cyanocobalamin, calcium carbonate and folic acid tablet, coated

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75854-307
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68 Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	75 mg
<b>CYANOCOBALAMIN</b> (UNII: P6 YC3EG204) (CYANOCOBALAMIN - UNII:P6 YC3EG204)	CYANOCOBALAMIN	12 ug
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>GINGER</b> (UNII: C5529G5JPQ)	500 mg
<b>LINGONBERRY</b> (UNII: 0UNK9RZQ7X)	25 mg
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	

**Product Characteristics**

<b>Color</b>	yellow	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	Prenate;AM
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-307-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/15/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/15/2013	

**Labeler** - Avion Pharmaceuticals, LLC (965450542)**Establishment**

Name	Address	ID/FEI	Business Operations

Revised: 1/2018

Avion Pharmaceuticals, LLC