

**PRENATE PIXIE- ascorbic acid, biotin, cholecalciferol, cyanocobalamin, folic acid, ferrous asparto glycinate, potassium iodide, pyridoxine hydrochloride, .alpha.-tocopherol acetate, dl-, docusate sodium and blueberry tablet, film 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 Pixie® 75854-0316**

**Rx Only**

**DESCRIPTION:** PRENATE PIXIE® is a prescription prenatal/postnatal multivitamin/mineral/essential fatty acid softgel. Each softgel is purple in color, opaque, and imprinted with “PIX”.

**Supplement Facts**

Serving Size: 1 Softgel

**Amount per Serving:**

		% Daily Value	% Daily Value (Pregnant & Lactating Women)
Vitamin C (as ascorbic acid)	30 mg	50%	50%
Biotin	75 mcg	25%	25%
Vitamin D3 (as cholecalciferol)	500 IU	125%	125%
Vitamin B12 (as cyanocobalamin)	13 mcg	217%	163%
Folate (as ((6S)-N5-methyltetrahydrofolic acid calcium salt (molar equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1 mg	250%	125%
Iron (as ferrous asparto glycinate) Sumalate <sup>®</sup>	10 mg	56%	56%
Iodine (as potassium iodide)	150 mcg	100%	100%
Vitamin B6 (as pyridoxine HCl)	5 mg	250%	200%
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU	33%	33%
Docosahexaenoic acid (DHA)	200 mg	†	†
Blueberry extract (vaccinium spp.)	5 mg	†	†

† Daily Value (DV) not established.

**OTHER INGREDIENTS:** Capsule gelatin (gelatin, glycerin, purified water, titanium dioxide, FD&C

red #40, caramel, and FD&C blue #1), palm shortening, soy lecithin, and yellow beeswax. PRENATE PIXIE® contains fish oil and soy.

**INDICATIONS:** PRENATE PIXIE® is a multivitamin/multimineral fatty acid 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.

**WARNING:** Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

**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.

**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.

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

**DOSAGE AND ADMINISTRATION:** Before, during and/or after pregnancy, one softgel daily or as directed by a physician.

**HOW SUPPLIED:** Bottles of 30 softgels (75854-0316-30). 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.

**STORAGE:** 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.**

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

Sumalate® is a registered trademark of Albion Laboratories, Inc., covered by one or more claims of U.S. Patent Nos. 5,516,925, 6,716,814, 8,007,846, and 8,425,956.

MANUFACTURED FOR:

Avion Pharmaceuticals, LLC  
Alpharetta, Georgia 30005

1-888-61-AVION

Rev. 0519-03

**CONTRAINDICATIONS:** PRENATE PIXIE® is contraindicated in patients with a known hypersensitivity to any of the ingredients.

75854-0316-30

Prenate pixie®

Robust Rx Prenatal Vitamin with  
11 concentrated nutrients and minerals

in a tiny softgel package

SUGAR FREE

GLUTEN FREE

LACTOSE FREE

Rx Only

Dietary Supplement

30 Softgels



## PRENATE PIXIE

ascorbic acid, biotin, cholecalciferol, cyanocobalamin, folic acid, ferrous asparto glycinate, potassium iodide, pyridoxine hydrochloride, .alpha.-tocopherol acetate, dl-, docusate sodium and blueberry tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75854-316
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	30 mg
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	75 ug
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	500 [iU]
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	400 ug

<b>FERROUS ASPARTO GLYCINATE</b> (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	10 mg
<b>POTASSIUM IODIDE</b> (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	5 mg
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WP17EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [iU]
<b>DOCUSATE SODIUM</b> (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	200 mg
<b>BLUEBERRY</b> (UNII: 253RUG1X1A) (BLUEBERRY - UNII:253RUG1X1A)	BLUEBERRY	5 mg
<b>LEVOMEFOLIC ACID</b> (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	

### Product Characteristics

<b>Color</b>	purple	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	22mm
<b>Flavor</b>		<b>Imprint Code</b>	PIX
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75854-316-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/15/2014	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/15/2014	

**Labeler** - Avion Pharmaceuticals, LLC (040348516)

### Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		040348516	manufacture(75854-316)

