

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.

PRENATE[®] Pixie 75854-0316

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 [®]	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.

PRENATE[®] PIXIE contains fish oil and soy.

OTHER INGREDIENTS: Bovine gelatin, glycerin, yellow beeswax, soy lecithin, vegetable

shortening, purified water, titanium dioxide, FD&C Red #40, caramel and FD&C Blue #1.

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.

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

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.

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.

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.

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.]

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.

PRENATE[®] Pixie is a registered trademark of Acella Pharmaceuticals, LLC. Under license from Acella Pharmaceuticals, LLC. All rights reserved.

MANUFACTURED FOR:

Avion Pharmaceuticals, LLC

Alpharetta, Georgia 30022

1-888-61-AVION

Rev. 1014

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 30 softgel container image

75854-0316-30

Prenate[®] pixie

**Robust Rx Prenatal Vitamin with
11 concentrated nutrients and minerals**

in a tiny softgel package

GLUTEN FREE

R_x Only

Prenatal Supplement

30 Softgels

Avion

PHARMACEUTICALS

Supplement Facts Serving Size: 1 Softgel
Amount per Serving:

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Docosahexaenoic acid (DHA)	200 mg
Blueberry extract (vaccinium spp.)	5 mg

OTHER INGREDIENTS: Bovine gelatin, glycerin, yellow beeswax, soy lecithin, vegetable shortening, purified water, titanium dioxide, FD&C Red #40, carmelum and FD&C Blue #1. **PRENATE[®] PIXIE** contains fish oil and soy.

75854-0316-30

Prenate[®] pixie

Robust Rx Prenatal Vitamin with 11 concentrated nutrients and minerals in a tiny softgel package

GLUTEN FREE

Rx Only
Prenatal Supplement
30 Softgels

DOSAGE AND ADMINISTRATION: One softgel daily, or as directed by a physician. See package insert for full prescribing information.

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.

KEEP OUT OF REACH OF CHILDREN.

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

Lot #:
Exp:

rev. 1214-01

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

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	30 mg
BIO TIN (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
FERROUS ASPARTO GLYCINATE (UNII: H7426RGB3L) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	10 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	5 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPIEW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	10 [iU]
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	200 mg
BLUEBERRY (UNII: 253RUG1X1A) (BLUEBERRY - UNII:253RUG1X1A)	BLUEBERRY	5 mg

LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug
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Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CORN OIL (UNII: 8470G57WFM)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CARAMEL (UNII: T9D99G2B1R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	purple	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	PIX
Contains			

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	08/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/14/2014	

Labeler - Avion Pharmaceuticals, LLC (965450542)

Establishment

Name	Address	ID/FEI	Business Operations
Avion Pharmaceuticals, LLC		965450542	manufacture(75854-316)