

PRENATE PIXIE- ascorbic acid, biotin, cholecalciferol, cyanocobalamin, levomefolate calcium, folic acid, ferrous asparto glycinate, potassium iodide, pyridoxine hydrochloride, .alpha.-tocopherol acetate, dl-, docosahexaenoic acid, 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

Rx Only Dietary Supplement

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”. Prenate Pixie® contains no ingredient made from gluten-containing grain (wheat, barley, or rye)

Supplement Facts			
Serving Size: 1 Softgel			
Servings Per Container:30			
	Amount Per Serving	% Daily Value	% Daily Value for Pregnant and Lactating Women
Vitamin C (as ascorbic acid)	30 mg	33%	25%
Vitamin D (as cholecalciferol)	12.5 mcg	63%	83%
Vitamin E (as dl-alpha tocopheryl acetate)	4.5 mg	30%	24%
Vitamin B ₆ (as pyridoxine HCl)	5 mg	294%	250%
Folate (as (6S)-N5-methyl-tetrahydrofolic acid calcium salt (equivalent to 600 mcg of folic acid) and folic acid, USP 400 mcg)	1700 mcg DFE	425%	283%
Vitamin B ₁₂ (as cyanocobalamin)	13 mcg	542%	464%
Biotin	75 mcg	250%	214%
Iron (as ferrous asparto glycinate) Sumalate®	10 mg	60%	37%
Iodine (as potassium iodide)	150 mcg	100%	52%
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: Beeswax, palm shortening and soy lecithin. Capsule (caramel, FD&C blue #1, FD&C red #40, gelatin, glycerin, purified water and titanium dioxide).

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.

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.

Biotin levels higher than the recommended daily allowance may cause interference with some laboratory tests, including cardiovascular diagnostic test (e.g. troponin) and hormone tests, and may lead to incorrect test results. Tell your healthcare provider about all prescription and over-the-counter medicines, vitamins, and dietary supplements that you take, including biotin.

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

L-0244 Rev. 0325-03

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, levomefolate calcium, folic acid, ferrous asparto glycinate, potassium iodide, pyridoxine hydrochloride, .alpha.-tocopherol acetate, dl-, docosahexaenoic acid, and blueberry tablet, film coated

Product Information

Product Type

HUMAN PRESCRIPTION DRUG

Item Code (Source)

NDC:75854-316

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	30 mg
BIOTIN (UNII: 6S06U10H04) (BIOTIN - UNII:6S06U10H04)	BIOTIN	75 ug
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	12.5 ug
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:GW89581OWR)	FERROUS CATION	10 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	150 ug
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	5 mg
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	4.5 mg
BLUEBERRY (UNII: 253RUG1X1A) (BLUEBERRY - UNII:253RUG1X1A)	BLUEBERRY	5 mg
DOCOSAHEXAENOIC ACID (UNII: ZAD90KH9JC) (DOCONEXENT - UNII:ZAD90KH9JC)	DOCOSAHEXAENOIC ACID	200 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	600 ug

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C00X)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CARAMEL (UNII: T9D99G2B1R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
BEESWAX (UNII: 2ZA36H0S2V)	
PALM SHORTENING (UNII: 5QUO05548Z)	

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	08/15/2014	

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)

Revised: 5/2025

Avion Pharmaceuticals, LLC