FLORIVA- vitamin a acetate, .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol, thiamine, riboflavin, niacinamide, pyridoxine, levomefolate glucosamine, folic acid, cyanocobalamin, biotin, zinc gluconate, cupric oxide, and sodium fluoride tablet, chewable BonGeo Pharmaceuticals, Inc.

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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### Floriva™ 0.5 mg TABLETS

Supplement Facts
Serving Size: 1 tablet
Servings Per Container: 9

Servings Per Container: 90		
	Amount per tablet	% Daily Value*
Vitamin A (50% beta carotene/50% acetate)	2000 IU	40%
Vitamin C (ascorbic acid)	75 mg	125%
Vitamin D3 (cholecalciferol)	600 IU	150%
Vitamin E (dl alpha tocopherol acetate)	20 IU	67%
Vitamin B1 (thiamine)	1.3 mg	87%
Vitamin B2 (riboflavin)	1.5 mg	88%
Niacin (nicotinamide)	15 mg	75%
Vitamin B6 (pyridoxine)	1.8 mg	90%
Folate (as 300 mcg Quatrefolic R ((6S-5-methyltetrahydrofolic acid, glucosamine salt <sup>†</sup> , molar equivalent to 162 mcg of folic acid) and 100 mcg of folic acid) Quatrefolic CAS #: 1181972-37-1	262 mcg	66%
Vitamin B12 (cyanocobalamin)	6 mcg	100%
Biotin	40 mcg	13%
Zinc (zinc gluconate)	5 mg	33%
Copper (cupric oxide)	1 mg	50%
Fluoride (sodium fluoride)	0.5 mg	†

<sup>\*</sup> Percent Daily Value (%DV) for Adults and Children 4 or more years of age based on a 2000 calorie diet.

### Other Ingredients

Natural berry flavor, bitterness masking agent, MCC, sucralose, talc, magnesium stearate, xylitol (DC and regular grade).

# Description

<sup>†</sup> Daily Value not established.

Off-white to pale yellow, speckled, berry flavored, hexagon shaped chewable tablet. Debossed "174" on one side and scored on the other.

#### **Directions**

**USE AS DIRECTED BY YOUR PHYSICIAN.** 

#### **Tamper Evident Feature**

Do not use if inner-seal beneath cap is missing or broken.

#### WARNING

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IF OVERDOSAGE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY 1-800-222-1222. TABLET SHOULD BE CHEWED. THIS TABLET, AS WITH ALL TABLETS, IS NOT RECOMMENDED FOR CHILDREN UNDER AGE OF 4 DUE TO RISK OF CHOKING.

#### **CAUTION**

Do not use this product if you are allergic to any of the ingredients. Take this product at least 2 hours before or after taking any products containing calcium (including milk, yogurt, other dairy products) or aluminum/magnesium hydroxide (e.g., certain antacids/laxatives). Prolonged daily ingestion of excessive fluoride may result in varying degrees of dental fluorosis. Account for all daily sources of fluoride intake.

#### OTHER INFORMATION

You may report serious side effects to 1-844-640-7607. Store in a cool, dry place at room temperature 20-25° Celsius (68-77° Fahrenheit) away from heat and sunlight. Store in original container.

The numeric identifier on this product's labeling is an assigned product code for use with pharmacy-level, health insurance and state level reimbursement programs and is not intended to denote registration with the FDA.

The manufacturer of this product requires that it be dispensed only under the order of a physician or licensed medical practitioner.

#### Manufactured for:

BonGeo Pharmaceuticals, Inc. Roseland, NJ 07068

#### Manufactured by:

Sancilio & Co., Inc. Riviera Beach, FL 33404

LOT/EXP

Quatrefolic Trademark and Patent property of Gnosis SpA.

#### PRINCIPAL DISPLAY PANEL - 90 Tablet Bottle Label

0.5 mg\* FLUORIDE TABLETS

BonGeo™ PHARMACEUTICALS

52796-174-90

Floriva™ 0.5 mg TABLETS

**Chewable Fluoride Multivitamin** 

Quatrefolic®

**Patent Ref.:** U.S. Patent No. 7,947,662; Other patents pending

# **Natural Berry Flavor**

Rx Dietary Supplement

90 Chewable Tablets

\*contains 0.5 mg fluoride from 1.1 mg sodium fluoride

• SUGAR FREE AND GLUTEN FREE • NO ARTIFICIAL COLORS OR DYES •





52796-174-90



#### R Dietary Supplement 90 Chewable Tablets

\*contains 0.5 mg fluoride from 1.1 mg sodium fluoride

SUGAR FREE AND GLUTEN FREE NO ARTIFICIAL COLORS OR DYES

# Supplement Facts

Serving Size: 1 tablet Servings Per Container: 90

A	mount per tablet	Value*
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Niacin (nicotinamide)	15 mg	75%
Vitamin B6 (pyridoxine)	1.8 mg	90%
Foliate (as 300 mog Quatrefolic R ((65-5-metry/tetrahydrofolic acid, glucosamin salt**, molar equivalent to 162 mog of folic acid) and 100 mog of folic acid) Quatrefolic CAS #: 1181972-37-1	e 262 mcg	66%
Vitamin B12 (cyanocobalamin)	6 mcg	100%
Biotin	40 mcg	13%
Zinc (zinc gluconate)	5 mg	33%
Copper (cupric oxide)	1 mg	50%
Fluoride (sodium fluoride)	0.5 mg	**

Percent Daily Value (%DV) for Adults and Children 4 or more years of age based on a Daily Value not established.

Other Ingredients:
Natural berry flavor, bitterness masking agent, MCC, sucralose, talc, magnesium stearate, xylitol (DC and regular grade).

#### Description:

Off-white to pale yellow, speckled, berry flavored, hexagon shaped chewable tablet. Debossed "174" on one side and scored on the other.

Quatrefolic Trademark and Patent property of Gnosis SpA.



Directions: USE AS DIRECTED BY YOUR PHYSICIAN.

Tamper Evident Feature: Do not use if inner-seal beneath cap is missing or broken.

WARNING: KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. IF OVERDOSAGE IS SUSPECTED, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY 1-800-222-1222. TABLET SHOULD BE CHEWED. THIS TABLET, AS WITH ALL TABLETS, IS NOT RECOMMENDED FOR CHILDREN UNDER AGE OF 4 DUE TO RISK OF CHOKING.

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The manufacturer of this product requires that it be dispensed only under the order of a physician or licensed medical practitioner.

Manufactured for: BonGeo Pharmaceuticals, Inc.

Manufactured by: Sancilio & Co., Inc. Riviera Beach, FL 33404

# Roseland, NJ 07068

#### **FLORIVA**

vitamin a acetate, .beta.-carotene, ascorbic acid, cholecalciferol, .alpha.-tocopherol, thiamine, riboflavin, niacinamide, pyridoxine, levomefolate glucosamine, folic acid, cyanocobalamin, biotin, zinc gluconate, cupric oxide, and sodium fluoride tablet, chewable

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Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:52796-174

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1000 [iU]	
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	1000 [iU]	
Ascorbic acid (UNII: PQ6CK8PD0R) (Ascorbic acid - UNII:PQ6CK8PD0R)	Ascorbic acid	75 mg	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	600 [iU]	
.ALPHATOCOPHEROL (UNII: H4N855PNZ1) (.ALPHATOCOPHEROL - UNII: H4N855PNZ1)	.ALPHATOCOPHEROL	20 [iU]	
THIAMINE (UNII: X66NSO3N35) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.3 mg	
RIBOFLAVIN (UNII: TLM29760FR) (Riboflavin - UNII:TLM29760FR)	RIBOFLAVIN	1.5 mg	
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	15 mg	
<b>PYRIDOXINE</b> (UNII: KV2JZ1BI6Z) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.8 mg	
<b>LEVOMEFOLATE GLUCOSAMINE</b> (UNII: Q65PL71Q1A) (LEVOMEFOLATE GLUCOSAMINE - UNII:Q65PL71Q1A)	LEVOMEFOLATE GLUCOSAMINE	162 ug	
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	100 ug	
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	6 ug	
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	40 ug	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC GLUCONATE	5 mg	
CUPRIC OXIDE (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
TALC (UNII: 7SEV7J4R1U)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
XYLITOL (UNII: VCQ006KQ1E)			

Product Characteristics			
Color	WHITE (Off white, speckled)	Score	2 pieces
Shape	HEXAGON (6 SIDED)	Size	13mm
Flavor	BERRY	Imprint Code	174
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52796-174- 90	90 in 1 BOTTLE; Type 0: Not a Combination Product	10/15/2014	

2	NDC:52796-174- 01	1 in 1 CARTON	10/15/2014	
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/15/2014	

# Labeler - BonGeo Pharmaceuticals, Inc. (964822022)

Revised: 2/2024 BonGeo Pharmaceuticals, Inc.