

FLORAFOL- multivitamin and fluoride supplement tablet
Pangea 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.

Florafol™

Pediatric (1.0 mg Fluoride) Multivitamin and Fluoride Chewable Tablet

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Supplement Facts

Serving Size: 1 Tablet

Servings Per Container: 30

Amount Per Serving		% Daily Values	
		%DV	%DV Children
		Children 4-8	9 years and older
Vitamin A (as Retinyl Acetate)	700 mcg	175%	117%
Vitamin B1 (as Thiamine Mononitrate)	1 mg	167%	111%
Vitamin B2 (as Riboflavin)	1 mg	167%	111%
Niacin (as Niacinamide)	12 mg	150%	100%
Vitamin B6 (as Pyridoxine HCl)	1.15 mg	192%	115%
Vitamin B12 (as Cyanocobalamin)	3.5 mcg	292%	194%
Folate (as L-Methylfolate, Calcium Salt Metafolin)	250 mcg DFE	125%	83%
Vitamin C (as Sodium Ascorbate)	70 mg	280%	156%
Vitamin D (as Cholecalciferol)	12 mcg	80%	80%
Vitamin E (as D-Alpha-Tocopherol)	11.5 mg	164%	105%
Fluoride (as Sodium Fluoride)	1.0 mg	100%	50%

Other Ingredients: Xylitol, Sorbitol, Citric Acid Anhydrous, Monk Fruit Juice, Berry Flavor, Beet Root Juice, Carrageenan, Magnesium Stearate, Stearic Acid

Allergens: Fish Oil

Caution: This product should be chewed and is not recommended for children under age 4 due to risk of choking.

Distributed by:
Pangea Pharmaceuticals, LLC

Brielle, NJ 08730
 1-855-892-8224
 www.florafolrx.com

PRINCIPAL DISPLAY PANEL - Multivitamin with 1.0 mg of Fluoride

81279-103-30

FloraFol

(Multivitamin with 1.0 mg of Fluoride) Chewable Tablet MULTIVITAMIN & FLUORIDE SUPPLEMENT BERRY FLAVOR

1.0 mg

30 Tablets

81279-103-30

FloraFolTM
 Pediatric

BERRY FLAVOR

30 Chewable Tablets
Pediatric Multivitamin & Fluoride 1 mg **FLUORIDE**

Dye Free Gluten Free Dairy Free

PANGEA PHARMACEUTICALS

CAUTION: NOT RECOMMENDED FOR KIDS UNDER FOUR (4) YEARS OF AGE DUE TO POTENTIAL CHOKING HAZARD

www.florafolrx.com

Manufactured for: Pangea Pharmaceuticals, LLC, Brielle, NJ 08730 Visit us online at www.florafolrx.com

Supplement Facts

Amount Per Serving	% Daily Values Children	
	4 to 8yrs	9yrs+
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Fluoride (as Sodium Fluoride)	1 mg	100% 50%

Other Ingredients: Xylitol, Sorbitol, Citric Acid Anhydrous, Monk Fruit, Berry Flavor, Beet Root Juice, Carrageenan, Magnesium Stearate, Stearic Acid Allergens: Fish Oil *DFE (dietary folate equivalents)

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FLORAFOL

multivitamin and fluoride supplement tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:81279-103
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	700 ug
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	12 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.15 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	3.5 ug
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	250 ug

ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	70 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	12 ng
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	11.5 mg
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	pink	Score	no score
Shape	ROUND	Size	11mm
Flavor	BERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81279-103-30	1 in 1 PACKAGE	08/01/2024	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2024	

Labeler - Pangea Pharmaceuticals, LLC (117751012)

Registrant - Pangea Pharmaceuticals, LLC (117751012)