

FLORAFOL FE PEDIATRIC 0.25 MG/ML MULTIVITAMIN AND FLUORIDE LIQUID DROPS- vitamin a (as retinyl palmitate) vitamin c (as ascorbic acid) vitamin d3 (as cholecalciferol) vitamin e (as d-alpha-tocopherol acetate) vitamin b1 (as thiamine hcl) vitamin b2 (as riboflavin phosphate sodium) niacin (as niacinamide) vitamin b6 (pyridoxine hcl) folate (as 69 mcg quatrefolic ((6s)-5 methyltetrahydrofolate, glucosamine salt, molar equivalent to 37.5 mcg of folic acid)) vitamin b12 (as cyanocobalamin) iron (as ferrous sulfate) fluoride (as sodium fluoride) solution/ drops

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™ FE Pediatric 0.25 mg/mL Multivitamin and Fluoride Liquid Drops

Supplement Facts		% Daily Value		
Serving Size : 1mL		Infants	Children	Children
Servings per container: 50		7-12	1-3 yrs	4-8 yrs
Amount per serving 1mL		months		
VITAMIN A (as Retinyl Palmitate)	450 mcg	90%	150%	113%
VITAMIN C (as Ascorbic Acid)	36 mg	72%	240%	144%
VITAMIN D3 (as Cholecalciferol)	10 mcg	100%	67%	67%
VITAMIN E (as d-Alpha-Tocopherol Acetate)	3.35 mg	45%	38%	32%
VITAMIN B1 (as Thiamine HCl)	0.5 mg	167%	100%	83%
VITAMIN B2 (as Riboflavin Phosphate Sodium)	0.6 mg	150%	120%	100%
NIACIN (as Niacinamide)	4 mg	100%	67%	50%
VITAMIN B6 (Pyridoxine HCl)	0.4 mg	133%	80%	67%
Folate (as 69 mcg Quatrefolic® ((6S)-5 Methyltetrahydrofolate, glucosamine salt, molar equivalent to 37.5 mcg of Folic Acid))	117 mcg DFE	147%	78%	59%
VITAMIN B12 (as Cyanocobalamin)	2 mcg	400%	222%	167%
Iron (as Ferrous Sulfate)	9.5 mg	86%	136%	95%
FLUORIDE (as Sodium Fluoride)	0.25 mg	50%	36%	25%

Other Ingredients: Purified Water, Glycerin, Sorbitol, Sucralose, Sodium Benzoate, Potassium Sorbate, Sodium Carbonate, Monoammonium glycyrrhizinate, Grape Flavor.

INDICATIONS AND USAGE

Florafol™ FE Pediatric 0.25 mg/mL Fluoride (with Iron), is a multivitamin and fluoride prescription product providing essential vitamins, minerals and fluoride.

CONTRAINDICATIONS

Do not use in areas where drinking water exceeds 0.6 ppm Fluoride. Do not administer to pediatric patients less than 6 months old.

PRECAUTIONS

General

Do not use this product if you are allergic to any of the ingredients. The suggested dose should not be exceeded, since dental fluorosis may result from continued ingestion of large amounts of fluoride. Do not eat or drink dairy products within one hour of fluoride administration since these may decrease effectiveness.

Folic Acid

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 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

Other Information

Call your doctor for medical advice about side effects. You may report serious side effects by calling Pangea Pharmaceuticals, LLC, at 1-855-892-8224.

WARNINGS

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, seek professional emergency assistance or contact a Poison Control Center immediately.

DOSAGE AND ADMINISTRATION

See schedule below to determine dosage. Administer orally as prescribed by a healthcare practitioner. Use with calibrated dropper for measuring doses.

Fluoride Ion Level In Drinking Water (ppm)*

Age	Less than 0.3ppm	0.3-0.6 ppm	Greater than 0.6 ppm
Birth-6 months	None	None	None
6 months-3 years	0.25 mg/day†	None	None
3-6 years	0.50 mg/day†	0.25 mg/day	None

6-16 years	1.0 mg/day	0.50 mg/day	None
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* 1.0 part per million (ppm) = 1 milligram/liter (mg/L)

† 2.2 mg sodium fluoride contains 1 mg fluoride ion

Dietary Fluoride Supplement dosing schedule approved by the American Dental Association (ADA), American Academy of Pediatrics (AAP) & American Academy of Pediatric Dentistry (AAPD).

DESCRIPTION

Florafol™ FE Pediatric 0.25 mg/mL Fluoride (with Iron), multivitamin and fluoride liquid drops is a dye free and gluten free grape flavored product.

HOW SUPPLIED

Florafol™ FE Pediatric 0.25 mg/mL Fluoride is supplied in 50 mL (1-2/3 fl. oz.) child-resistant bottles with accompanying calibrated dropper (Product Code: 81279-101-50).

Rx Only

STORAGE

Store in a cool, dry place at room temperature 68 °F to 77 °F (20 °C to 25 °C) away from direct heat and sunlight.

Do not refrigerate this product.

SHAKE WELL BEFORE USE

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) since these may decrease effectiveness. Prolonged daily ingestion of excessive fluoride may result in varying degrees of dental fluorosis.

TAMPER EVIDENT

Do not use if seal is broken or missing.

Quatrefolic® is a registered trademark of Gnosis, SpA.

Manufactured for:
Pangea Pharmaceuticals, LLC,
Brielle, NJ 08730

Rev 12/2023

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

81279-101-50

FloraFolTM Fe
Pediatric

MULTIVITAMIN & FLUORIDE LIQUID DROPS



Grape Flavor

Dye Free • Gluten Free

0.25 mg/mL Fluoride

NOT SUBSTITUTABLE

Contains



Quatrefolic® is a Registered Trademark of Crocea S.p.A.

R_x only

1.66 FL OZ (50mL)



with Iron

Supplement Facts

Serving Size: 1mL (Mark on Dropper)

Servings Per Container: 50

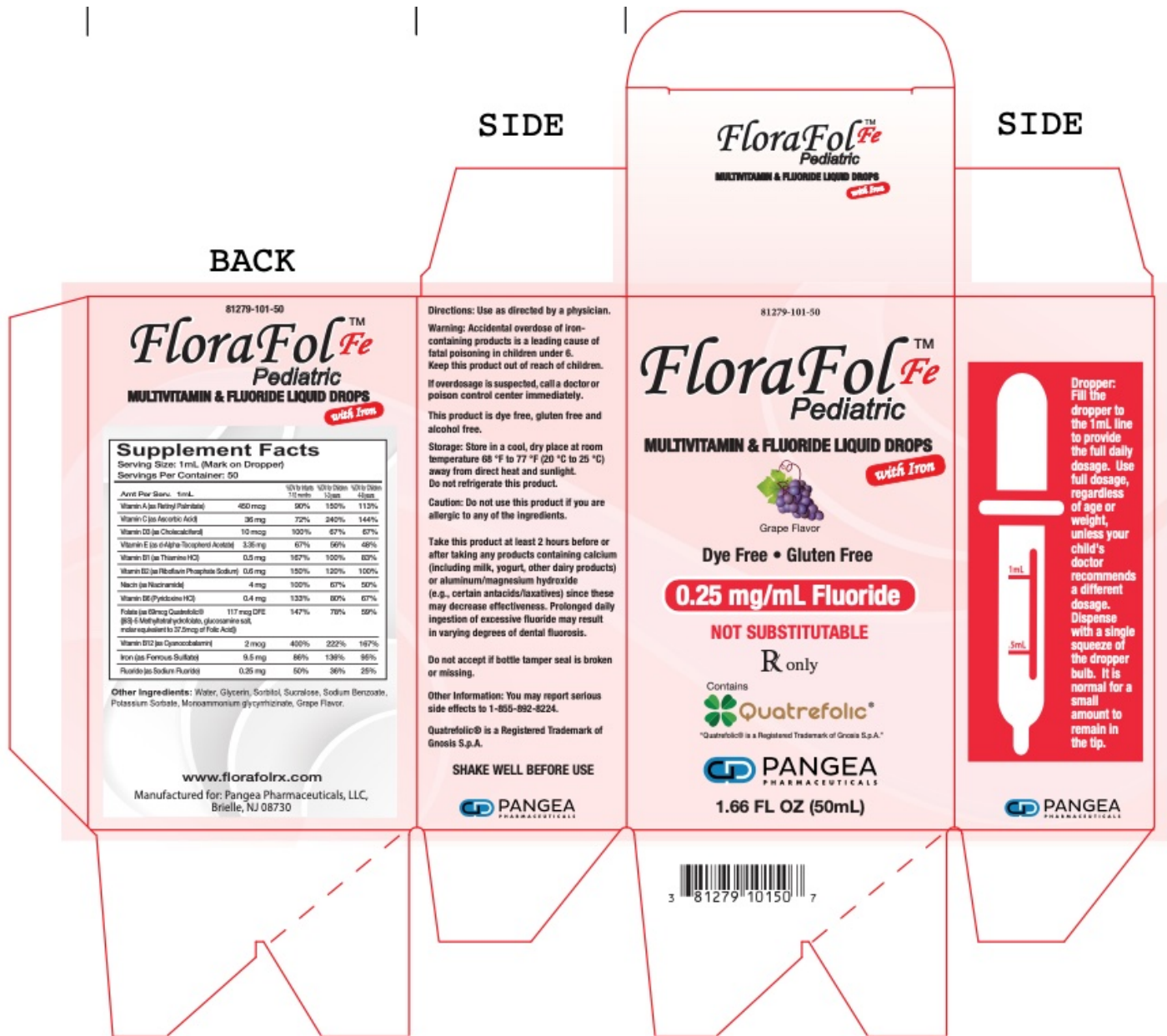
Amt Per Serv. 1mL	%DV for Children			
	7-12 months	1-5 years	6-12 years	
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Other Ingredients: Water, Glycerin, Sorbitol, Sucralose, Sodium Benzoate, Potassium Sorbate, Monoammonium glycyrrhizinate, Grape Flavor.

Manufactured for: Pangea Pharmaceuticals, LLC, Brielle, NJ 08730





81279-101-50
Florafol™ FE
 PEDIATRIC
 Multivitamin & Fluoride Liquid Drops
 0.25 mg/mL Fluoride
 Dye Free • Gluten Free
Rx Only • Grape Flavor
 50 mL
 (1⅔ fl oz.)

FLORAFOL FE PEDIATRIC 0.25 MG/ML MULTIVITAMIN AND FLUORIDE LIQUID DROPS

vitamin a (as retinyl palmitate) vitamin c (as ascorbic acid) vitamin d3 (as cholecalciferol) vitamin e (as d-alpha-tocopherol acetate) vitamin b1 (as thiamine hcl) vitamin b2 (as riboflavin phosphate sodium) niacin (as niacinamide) vitamin b6 (pyridoxine hcl) folate (as 69 mcg quatrefolic ((6s)-5 methyltetrahydrofolate, glucosamine salt, molar equivalent to 37.5 mcg of folic acid)) vitamin b12

(as cyanocobalamin) iron (as ferrous sulfate) fluoride (as sodium fluoride) solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:81279-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	450 ug in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg in 1 mL
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug in 1 mL
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	3.35 mg in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	0.5 mg in 1 mL
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	0.6 mg in 1 mL
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	4 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	0.4 mg in 1 mL
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	117 ug in 1 mL
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	2 ug in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	9.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
POTASSIUM CARBONATE (UNII: BQN1B9B9HA)	
.ALPHA.-D-GLUCURONIC ACID (UNII: M7Y086VB5G)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor	grape	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81279-101-50	1 in 1 CARTON	12/20/2023	
1		50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/20/2023	

Labeler - Pangea Pharmaceuticals, LLC (117751012)

Revised: 12/2023

Pangea Pharmaceuticals, LLC