

QUFLORA FE PEDIATRIC DROPS- vitamin a palmitate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacinamide, pantothenic acid, pyridoxine hydrochloride, biotin, levomefolate glucosamine, cyanocobalamin, ferrous sulfate, and sodium fluoride liquid

Carwin Pharmaceutical Associates, 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.

Quflora[®] FE Pediatric Liquid Drops

Supplement Facts			
Serving Size: 1 mL (Mark on dropper)			
Servings per Container: 50			
Amount Per 1 mL		% DV Children 6 months to under 4 years of age	% DV for Adults and Children 4 or more years of age
Vitamin A (as Palmitate)	1500 IU	60%	30%
Vitamin C (as Ascorbic Acid)	36 mg	90%	60%
Vitamin D3 (as Cholecalciferol)	400 IU	100%	100%
Vitamin E (as D-Alpha-Tocopheryl Acetate)	5 IU	50%	17%
Thiamin (as Thiamine HCl, Vitamin B1)	0.5 mg	71%	33%
Riboflavin (Vitamin B2)	0.6 mg	75%	35%
Niacin (as Niacinamide)	4 mg	45%	20%
Pantothenic Acid	1 mg	20%	10%
Vitamin B6 (as Pyridoxine HCl)	0.4 mg	57%	20%
Biotin	3 mcg	2%	1%
Folate (as 69 mcg Quatrefolic [®] ((6S)-5 Methyltetrahydrofolic acid, glucosamine salt, molar equivalent to 37.5 mcg of Folic Acid))	37.5 mcg	20%	10%
Vitamin B12 (as Cyanocobalamin)	2 mcg	67%	33%
Iron (as Ferrous Sulfate)	9.5 mg	95%	53%
Fluoride (as Sodium Fluoride)	0.25 mg	*	*

* Daily Value not established

Other Ingredients: Purified Water, Citric Acid, Glycerin, Grape Flavor, Sorbitol, Propylene Glycol, Sucralose, Sodium Benzoate.

INDICATIONS AND USAGE

Quflora[®] FE Pediatric Liquid Drops is a prescription dietary supplement providing essential vitamins, iron and fluoride.

CONTRAINDICATIONS

Do not use in areas where drinking water exceeds 0.6 ppm F. 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.

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.

Other information

Call your doctor for medical advice about side effects. You may report serious side effects or obtain product information by calling Carwin Pharmaceutical Associates, LLC at 1-844-700-5011.

DOSAGE AND ADMINISTRATION

See schedule below to determine dosage. Administer orally as prescribed by a healthcare practitioner. Use with calibrated dropper for measuring doses. Each dropper full 1mL contains: 0.55 mg sodium fluoride, USP.

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

* 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

Quflora[®] FE Pediatric Liquid Drops is a yellow, dye free, grape flavored liquid.

HOW SUPPLIED

Quflora[®] FE Pediatric Liquid Drops in a 50 mL (1 fl. oz.) child-resistant bottle with accompanying calibrated dropper. (Product Code: 15370-102-50).

Rx Only

STORAGE

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

SHAKE WELL BEFORE USING

TAMPER EVIDENT

Do not use if seal is broken or missing.

Quatrefolic[®] is a registered trademark of Gnosis, SpA. Covered by one or more claims of U.S. Patent # 7,947,662 CAS# 1181972-37-1

Manufactured for:

Carwin Pharmaceutical Associates, LLC

Hazlet, NJ 07730

www.carwinpharma.com

Rev. 3/17

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

15370-102-50

QUfLORA[®]

FE

PEDIATRIC

Liquid Drops

Dietary Supplement with

Iron & 0.25 mg/mL Fluoride

Rx Only • Grape Flavor

50 mL

(1 fl oz.)

carwin

PHARMACEUTICAL ASSOCIATES

Quatrefolic[®]

15370-102-50

QUFLORA[®] FE
PEDIATRIC
Liquid Drops

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TAMPER EVIDENT: Do not use if seal is broken or missing.

Shake well before use.

Manufactured for:
Carwin Pharmaceutical
Associates, LLC
Hazlet, NJ 07730

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QUTORA[®] PEDIATRIC
Liquid Drops
 Dietary Supplement with
 Iron & 0.25 mg/mL Fluoride

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Other Ingredients: Purified Water, Citric Acid, Glycerin, Grape Flavor, Sorbitol, Propylene Glycol, Sucralose, Sodium Benzoate.

For complete product information, please reference the package insert located inside the box.



CALIBRATED DROPPER ENCLOSED



Lot:
Exp:

COATING FREE AREA

COATING FREE AREA



9 6 6 6 5 2



QUFLORA FE PEDIATRIC DROPS

vitamin a palmitate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacinamide, pantothenic acid, pyridoxine hydrochloride, biotin, levomefolate glucosamine, cyanocobalamin, ferrous sulfate, and sodium fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:15370-102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) (VITAMIN A - UNII:81G40H8B0T, RETINOL - UNII:G2SH0XKK91)	VITAMIN A	1500 [iU] 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	400 [iU] in 1 mL
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	5 [iU] 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
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	1 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	0.4 mg in 1 mL
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	3 ug in 1 mL
LEVOMEFOLATE GLUCOSAMINE (UNII: Q65PL71Q1A) (LEVOMEFOLATE GLUCOSAMINE - UNII:Q65PL71Q1A)	LEVOMEFOLATE GLUCOSAMINE	37.5 ug in 1 mL
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	2 ug in 1 mL
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	9.5 mg in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE (UNII: AUG1H506LY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

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:15370-102-50	1 in 1 CARTON	04/21/2017	
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		04/21/2017	

Labeler - Carwin Pharmaceutical Associates, LLC (079217215)

Revised: 4/2017

Carwin Pharmaceutical Associates, LLC