QUFLORA FE PEDIATRIC DROPS- vitamin a palmitate, as corbic 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	$0.50 \text{ mg/day}^{\dagger}$	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)

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.

^{† 2.2} mg sodium fluoride contains 1 mg fluoride ion

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 $^{\circledR}$ 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®

FΕ

PEDIATRIC

Liquid Drops

Dietary Supplement with Iron & 0.25 mg/mL Fluoride

Rx Only • Grape Flavor

50 mL

(11 fl oz.)

carwin

PHARMACEUTICAL ASSOCIATES

Quatrefolic®

15370-102-50



Dietary Supplement with Iron & 0.25 mg/mL Fluoride

Rx Only . Grape Flavor







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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.

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

Shake well before use.

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

*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







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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.

* Daily Value not established

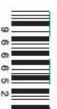


CALIBRATED DROPPER ENCLOSED

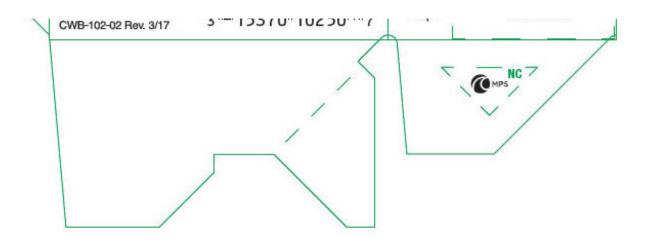
1 mL .5

Lot:

COATING FREE AREA



COATING FREE AREA



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			

Ingredient Name	Basis of Strength	Strength
VITAMIN A PALMITATE (UNII: 1D1K0 N0 VVC) (VITAMIN A - UNII:8 1G40 H8 B0 T, RETINOL - UNII:G2S H0 XKK9 1)	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
.ALPHATOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) (.ALPHATOCOPHEROL, D UNII:N9PR3490H9)	.ALPHATOCOPHEROL, D-	5 [iU] in 1 mL
THIAMINE HYDRO CHLO RIDE (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: 25X5118 RD4) (NIACINAMIDE - UNII:25X5118 RD4)	NIACINAMIDE	4 mg in 1 mL
PANTO THENIC ACID (UNII: 19 F5 HK2737) (PANTO THENIC ACID - UNII: 19 F5 HK2737)	PANTOTHENIC ACID	1 mg in 1 mL
PYRIDO XINE HYDRO CHLO RIDE (UNII: 68 Y4CF58BV) (PYRIDO XINE - UNII: KV2JZ1BI6Z)	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
CYANO CO BALAMIN (UNII: P6 YC3EG204) (CYANO COBALAMIN - UNII:P6 YC3EG204)	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 MO NO HYDRATE (UNII: 2968 PHW8 QP)	
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:153	370-102-	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		0 4/2 1/2 0 17		

Labeler - Carwin Pharmaceutical Associates, LLC (079217215)

Revised: 4/2017 Carwin Pharmaceutical Associates, LLC