

QUFLORA PEDIATRIC DROPS- vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, levomefolic acid, cyanocobalamin, magnesium oxide, cupric 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.

Quatrefolic® 0.5 mg/mL F* Pediatric Fluoride Drops

Supplement Facts			
Serving Size: 1 mL			
Servings Per Container: 50			
Amount Per 1 mL		% Daily Value Children 6 months to under 4 years of age	% Daily Value for Adults and Children 4 or more years of age
Vitamin A (as Acetate)	1,100 IU	44%	22%
Vitamin C (as Ascorbic Acid)	45 mg	113%	75%
Vitamin D3 (as Cholecalciferol)	400 IU	100%	100%
Vitamin E (as D-Alpha-Tocopheryl Acetate)	12 IU	120%	40%
Thiamin (as Thiamine HCl, Vitamin B1)	1 mg	143%	67%
Riboflavin (Vitamin B2)	1 mg	125%	59%
Niacin (as Niacinamide)	2 mg	22%	10%
Vitamin B6 (as Pyridoxine HCl)	1 mg	143%	50%
Folate (as 150 mcg Quatrefolic® ((6S)-5-methyltetrahydrofolic acid, glucosamine salt*, molar equivalent to 81 mcg of Folic Acid))	81 mcg	41%	20%
Vitamin B12 (as Cyanocobalamin)	3 mcg	100%	50%
Magnesium (as Magnesium Oxide)	12 mg	6%	3%
Copper (as Cupric Sulfate)	1 mg	100%	50%
Fluoride (as Sodium Fluoride)	0.5 mg	*	*

* Daily Value (DV) not established

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

INDICATIONS AND USAGE

Quflora® 0.5 mg/mL F* Pediatric Drops is a prescription dietary supplement providing essential vitamins, minerals 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.

Other information

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

WARNINGS

Keep out of the 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

* 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® 0.5 mg/mL F* Pediatric Drops is a light brown, dye free, grape flavored liquid.

HOW SUPPLIED

Quflora® 0.5 mg/mL F* Pediatric Drops in 50 mL (1 2/3 FL. OZ.) child-resistant bottles with accompanying calibrated dropper (Product Code: 15370-101-50).

Rx Only

STORAGE

Store at controlled room temperature 20°C to 25°C (68°F to 77°F). Protect from light, moisture and heat.

SHAKE 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

CAR-101-02
Rev. 5/17

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton

15370-101-50

QUfLORA™
PEDIATRIC
Liquid Drops

Dietary Supplement
0.5 mg/mL Fluoride

Each dropperful (1 mL) contains:
1.1 mg sodium fluoride, USP

Rx Only • Grape Flavor

50 mL
(1 fl oz.)

carwin
PHARMACEUTICAL ASSOCIATES

Quatrefolic®



QUFLORA PEDIATRIC DROPS

vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol acetate, d-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, levomefolic acid, cyanocobalamin, magnesium oxide, cupric sulfate, and sodium fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:15370-101
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
		100.0000

VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	100 [iU] in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	45 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-	12 [iU] in 1 mL
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1 mg in 1 mL
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1 mg in 1 mL
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	2 mg in 1 mL
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	1 mg in 1 mL
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	81 ug in 1 mL
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	3 ug in 1 mL
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	12 mg in 1 mL
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg in 1 mL
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GRAPE (UNII: 6X543N684K)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15370-101-50	1 in 1 CARTON	07/15/2014	
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		07/15/2014	

