

QUFLORA PEDIATRIC- vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, dl-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, levomefolic acid, folic acid, cyanocobalamin, magnesium oxide, cupric sulfate, and sodium fluoride tablet, chewable

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™ Pediatric Chewable Tablets

Supplement Facts		
Serving Size: 1 Tablet		
Servings per Container: 30		
	Amount per Serving	% Daily Value*
Vitamin A (as Acetate)	1,200 IU	24%
Vitamin C (as Ascorbic Acid)	60 mg	100%
Vitamin D3 (as Cholecalciferol)	400 IU	100%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	15 IU	50%
Thiamin (as Thiamine HCl, Vitamin B1)	1.2 mg	80%
Riboflavin (Vitamin B2)	1.3 mg	76%
Niacin (as Niacinamide)	5 mg	25%
Vitamin B6 (as Pyridoxine HCl)	1.5 mg	75%
Folate (as 200 mcg Quatrefolic® ((6S-5-methyltetrahydrofolic acid, glucosamine salt, molar equivalent to 108 mcg of Folic Acid), and 100 mcg of folic acid)	208 mcg	52%
Vitamin B12 (as Cyanocobalamin)	4 mcg	67%
Magnesium (as Magnesium Oxide)	15 mg	4%
Copper (as Cupric Sulfate)	1 mg	50%
Fluoride (as Sodium Fluoride)	0.5 mg	†

* %Daily Value for Adults and Children 4 or more years of age

† Daily Value not established

Other Ingredients: Citric acid, fumed silica, magnesium stearate, microcrystalline cellulose, natural grape flavor, silicon dioxide, stearic acid, sucralose, sucrose and xylitol.

INDICATIONS AND USAGE

Quflora™ Pediatric Chewable Tablets with 0.5 mg Fluoride is a prescription dietary fluoride supplement providing twelve essential vitamins and minerals.

CONTRAINDICATIONS

Quflora™ Pediatric Chewable Tablets with 0.5 mg Fluoride should not be used by patients with a known history of hypersensitivity to any of the listed ingredients.

PRECAUTIONS

General

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. Incompatibility of fluoride with dairy foods has been reported due to formation of calcium fluoride which is poorly absorbed. Your healthcare practitioner can prescribe the correct dosage.

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.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported. Call your doctor for medical advice about side effects. You may report side effects or obtain product information 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. This product should be chewed and is not recommended for children under age 4.

DOSAGE AND ADMINISTRATION

One tablet daily or as prescribed by your healthcare practitioner. Each tablet contains 0.5 mg fluoride ion (F) from 1.1 mg sodium fluoride (NaF).

DESCRIPTION

Quflora™ Pediatric Chewable Tablets with 0.5 mg Fluoride is a yellow round tablet imprinted "104".

HOW SUPPLIED

Quflora™ Pediatric Chewable Tablets with 0.5 mg Fluoride available in child-resistant bottles of 30 (Product Code: 15370-104-30).

Rx Only

STORAGE

Store at controlled room temperature 20° C to 25° C (68° F to 77° F), excursions permitted between 15° C and 30° C (59° F and 86° F). Protect from light, moisture and excessive heat.

KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.

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

Made in Canada

Rev. 4/16

PRINCIPAL DISPLAY PANEL - 0.25 mg Tablet Bottle Label

15370-103-30

QUFLORA™
PEDIATRIC
Chewable Tablets

Multivitamin with
0.25 mg Fluoride

Each chewable tablet contains:
0.55 mg sodium fluoride, USP

Rx Only • Grape Flavor

30 Tablets

carwin
PHARMACEUTICAL ASSOCIATES

15370-103-30

QUFLORA™
PEDIATRIC
Chewable Tablets

Multivitamin with
0.25 mg Fluoride

Each chewable tablet contains:
0.55 mg sodium fluoride, USP

Rx Only • Grape Flavor

30 Tablets

carwin
PHARMACEUTICAL ASSOCIATES

Supplement Facts		
	Amount per Serving	% Daily Value*
Vitamin A (as Acetate)	1,200 IU	24%
Vitamin C (as Ascorbic Acid)	60 mg	100%
Vitamin D3 (as Cholecalciferol)	400 IU	100%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	15 IU	50%
Thiamin (as Thiamine HCl, Vitamin B1)	1.2 mg	80%
Riboflavin (Vitamin B2)	1.3 mg	76%
Niacin (as Niacinamide)	5 mg	25%
Vitamin B6 (as Pyridoxine HCl)	1.5 mg	75%
Folate (as 200 mcg Quatrefolic® (6S-5-methyltetrahydrofolic acid, glucosamine salt, and 100 mcg of folic acid))	208 mcg	52%
Vitamin B12 (as Cyanocobalamin)	4 mcg	67%
Magnesium (as Magnesium Oxide)	15 mg	4%
Copper (as Cupric Sulfate)	1 mg	50%
Fluoride (as Sodium Fluoride)	0.25 mg	†

*% Daily Value for Adults and Children 4 or more years of age
† Daily Value not established

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Rev. Date: 04/16

PRINCIPAL DISPLAY PANEL - 0.5 mg Tablet Bottle Label

15370-104-30

QUFLORA™
PEDIATRIC
Chewable Tablets

**Multivitamin with
0.5 mg Fluoride**

Each chewable tablet contains:
1.1 mg sodium fluoride, USP

Rx Only • Grape Flavor

30 Tablets

carwin

PHARMACEUTICAL ASSOCIATES

15370-104-30

QUFLORA™
PEDIATRIC
Chewable Tablets

**Multivitamin with
0.5 mg Fluoride**

Each chewable tablet contains:
1.1 mg sodium fluoride, USP

Rx Only • Grape Flavor

30 Tablets



carwin
PHARMACEUTICAL ASSOCIATES

Lot No.:
Exp Date:

Supplement Facts		
	Amount per Serving	% Daily Value*
Vitamin A (as Acetate)	1,200 IU	24%
Vitamin C (as Ascorbic Acid)	60 mg	100%
Vitamin D3 (as Cholecalciferol)	400 IU	100%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	15 IU	50%
Thiamin (as Thiamine HCl, Vitamin B1)	1.2 mg	80%
Riboflavin (Vitamin B2)	1.3 mg	76%
Niacin (as Niacinamide)	5 mg	25%
Vitamin B6 (as Pyridoxine HCl)	1.5 mg	75%
Folate (as 200 mcg Quatrefolic® (6S-5- methyltetrahydrofolic acid, glucosamine salt, molar equivalent to 100 mcg of Folic Acid), and 100 mcg of folic acid)	208 mcg	52%
Vitamin B12 (as Cyanocobalamin)	4 mcg	67%
Magnesium (as Magnesium Oxide)	15 mg	4%
Copper (as Cupric Sulfate)	1 mg	50%
Fluoride (as Sodium Fluoride)	0.5 mg	†

*%Daily Value for Adults and Children 4 or more years of age
† Daily Value not established

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Rev. Date:
04/16

PRINCIPAL DISPLAY PANEL - 1 mg Tablet Bottle Label

15370-105-30

QUFLORA™
PEDIATRIC
Chewable Tablets

**Multivitamin with
1 mg Fluoride**

Each chewable tablet contains:
2.2 mg sodium fluoride, USP

Rx Only • Grape Flavor

30 Tablets

carwin

PHARMACEUTICAL ASSOCIATES

15370-105-30

QUFLORA™
PEDIATRIC
Chewable Tablets

**Multivitamin with
1 mg Fluoride**

Each chewable tablet contains:
2.2 mg sodium fluoride, USP
Rx Only • Grape Flavor

30 Tablets

 **carwin**
PHARMACEUTICAL ASSOCIATES

Supplement Facts		Serving Size: 1 Tablet Servings per Container: 30	
	Amount per Serving	% Daily Value*	
Vitamin A (as Acetate)	1,200 IU	24%	
Vitamin C (as Ascorbic Acid)	60 mg	100%	
Vitamin D3 (as Cholecalciferol)	400 IU	100%	
Vitamin E (as DL-Alpha Tocopheryl Acetate)	15 IU	50%	
Thiamin (as Thiamine HCl, Vitamin B1)	1.2 mg	80%	
Riboflavin (Vitamin B2)	1.3 mg	76%	
Niacin (as Niacinamide)	5 mg	25%	
Vitamin B6 (as Pyridoxine HCl)	1.5 mg	75%	
Folate (as 200 mcg Quatrefolic® (6S-5-methyltetrahydrofolic acid, glucosamine salt, and 100 mcg of folic acid))	208 mcg	52%	
Vitamin B12 (as Cyanocobalamin)	4 mcg	67%	
Magnesium (as Magnesium Oxide)	15 mg	4%	
Copper (as Cupric Sulfate)	1 mg	50%	
Fluoride (as Sodium Fluoride)	1 mg	†	

*%Daily Value for Adults and Children 4 or more years of age
† Daily Value not established

Rev. Date: 04/16



Lot No.:
Exp Date:

QUFLORA PEDIATRIC

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:15370-103
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	1200 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	15 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.2 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	1.5 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	108 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	100 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4 ug
MAGNESIUM OXIDE (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	15 mg
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg

Inactive Ingredients

Ingredient Name	Strength
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GRAPE (UNII: 6X543N684K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	103
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15370-103-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/06/2014	

QUFLORA PEDIATRIC

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:15370-104
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	1200 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	15 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.2 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	5 mg

PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	1.5 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	108 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	100 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	15 mg
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
GRAPE (UNII: 6X543N684K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	104
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15370-104-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/06/2014	

QUFLORA PEDIATRIC

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

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:15370-105
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	1200 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	15 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.2 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.3 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	1.5 mg
LEVOMEFOLIC ACID (UNII: 8S95DH25XC) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLIC ACID	108 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	100 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	15 mg
CUPRIC SULFATE (UNII: LRX7AJ16DT) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	1 mg
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg

Inactive Ingredients	
Ingredient Name	Strength
GRAPE (UNII: 6X543N684K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor	GRAPE	Imprint Code	105
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:15370-105-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/06/2014	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/06/2014	

Labeler - CarWin Pharmaceutical Associates, LLC (079217215)

Revised: 3/2018

CarWin Pharmaceutical Associates, LLC