

QUFLORA FE- vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, dl-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, levomefolate glucosamine, cyanocobalamin, biotin, calcium pantothenate, iron pentacarbonyl, zinc oxide, copper, and sodium fluoride tablet, chewable
CarWin Pharmaceutical Associates, LLC

QUFLORA™ FE
Chewable Tablets

Supplement Facts		
Serving Size: 1 Tablet		
Servings per Container: 30		
	Amount per Serving	% Daily Value*
Vitamin A (as Acetate)	2500 IU	50%
Vitamin C (as Ascorbic Acid)	100 mg	167%
Vitamin D3 (as Cholecalciferol)	600 IU	150%
Vitamin E (as DL-Alpha Tocopheryl Acetate)	30 IU	100%
Thiamine (as Thiamine HCl)	1.5 mg	100%
Riboflavin (Vitamin B2)	1 mg	59%
Niacin (as Niacinamide)	20 mg	100%
Vitamin B6 (as Pyridoxine HCl)	2 mg	100%
Folate (as 400 mcg Quatrefolic® ((6S-5 methyltetrahydrofolic acid, glucosamine salt, molar equivalent 216 mcg of Folic Acid)	216 mcg	54%
Vitamin B12 (as Cyanocobalamin)	9 mcg	150%
Biotin	45 mcg	15%
Pantothenic Acid (as D-Calcium Pantothenate)	10 mg	100%
Iron (as Carbonyl iron)	9 mg	50%
Zinc (as Zinc oxide)	12 mg	80%
Copper (as Copper HVP chelate)	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

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

INDICATIONS AND USAGE

Quflora™ FE Chewable Tablets Multivitamin with Iron and Fluoride 0.25mg is a prescription dietary fluoride supplement providing essential vitamins and minerals.

CONTRAINDICATIONS

Quflora™ FE Chewable Tablets Multivitamin with Iron and Fluoride 0.25 mg 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.

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.

DOSAGE AND ADMINISTRATION

One tablet daily or as prescribed by your healthcare practitioner. This product should be chewed and is not recommended for children under age 4.

DESCRIPTION

Quflora™ FE Chewable Tablets is a gray with yellowish tint, round tablet imprinted "120".

HOW SUPPLIED

Quflora™ FE Chewable Tablets are available in child-resistant bottles of 30 (Product Code: 15370-120-30).

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.

THIS PRODUCT CONTAINS IRON.

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. 5/16

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

15370-120-30

QUFLORA™ FE
Chewable Tablets

**Multivitamin with
Iron & Fluoride 0.25 mg**

Rx Only • Grape Flavor

30 Tablets

carwin
PHARMACEUTICAL ASSOCIATES

Supplement Facts		
	Amount per Serving	% Daily Value*
Serving Size: 1 Tablet Servings per Container: 30		
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Vitamin C (as Ascorbic Acid)	100 mg	167%
Vitamin D3 (as Cholecalciferol)	600 IU	150%
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QUFLORA FE

vitamin a acetate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, dl-, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, levomefolate glucosamine, cyanocobalamin, biotin, calcium pantothenate, iron pentacarbonyl, zinc oxide, copper, and sodium fluoride tablet, chewable

Product Information

Product Type

DIETARY SUPPLEMENT

Item Code (Source)

NHRIC:15370-120

Route of Administration	ORAL
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Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2500 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	100 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	600 [iU]
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 [iU]
THIAMINE HYDROCHLORIDE (UNII: M572600E5P) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE HYDROCHLORIDE	1.5 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	2 mg
LEVOMEFOLATE GLUCOSAMINE (UNII: Q65PL71Q1A) (LEVOMEFOLATE GLUCOSAMINE - UNII:Q65PL71Q1A)	LEVOMEFOLATE GLUCOSAMINE	216 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	9 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	45 ug
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (PANTOTHENIC ACID - UNII:19F5HK2737, CALCIUM CATION - UNII:2M83C4R6ZB)	PANTOTHENIC ACID	10 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	9 mg
ZINC OXIDE (UNII: SO2LOH54Z) (ZINC OXIDE - UNII:SO2LOH54Z)	ZINC OXIDE	12 mg
COPPER (UNII: 789U1901C5) (COPPER - UNII:789U1901C5)	COPPER	1 mg
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg

Inactive Ingredients	
Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
GRAPE (UNII: 6X543N684K)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:15370-120-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		07/12/2016	

Supplement Facts**Serving Size :****Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	14 mm	
imprint		
flavor		

Labeler - CarWin Pharmaceutical Associates, LLC (079217215)

Revised: 7/2016

CarWin Pharmaceutical Associates, LLC