

MULTI VITAMIN WITH FLUORIDE- multi vitamin with fluoride tablet, chewable
Qualites t Pharmaceuticals

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.

MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE

Rx only

Nutrition Facts				
Dosage Size 1 Chewable Tablet				
Amount Per Tablet	1 mg	0.5 mg	0.25 mg	%DV Adults and Children 4 Years or More
Vitamin A	2500 IU	2500 IU	2500 IU	50%
Vitamin C	60 mg	60 mg	60 mg	100%
Vitamin D	400 IU	400 IU	400 IU	100%
Vitamin E	15 IU	15 IU	15 IU	50%
Thiamin	1.05 mg	1.05 mg	1.05 mg	70%
Riboflavin	1.2 mg	1.2 mg	1.2 mg	70%
Niacin	13.5 mg	13.5 mg	13.5 mg	68%
Vitamin B6	1.05 mg	1.05 mg	1.05 mg	53%
Folate	0.3 mg	0.3 mg	0.3 mg	75%
Vitamin B12	4.5 mcg	4.5 mcg	4.5 mcg	75%
Fluoride	1 mg	0.5 mg	0.25 mg	*

*Daily Value (DV) not established

Active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Other Ingredients:

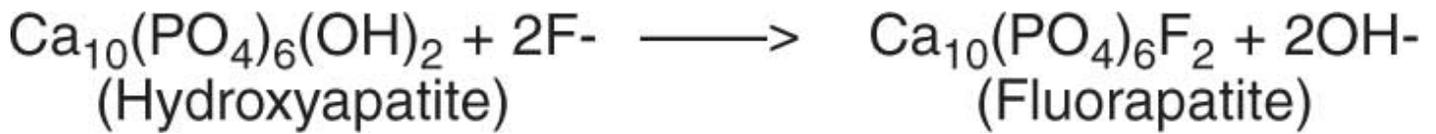
Artificial grape flavor, ascorbic acid, cholecalciferol, compressible sugar, D&C Red #7 calcium lake, FD&C Blue #1 aluminum lake, folic acid, magnesium stearate, microcrystalline cellulose, niacinamide, polyethylene glycol, pyridoxine, riboflavin, sodium ascorbate, stearic acid, thiamine, vitamin A acetate, vitamin B12 and vitamin E acetate.

CLINICAL PHARMACOLOGY

It is well established that fluoridation of the water supply (1 ppm fluoride) during the period of tooth development leads to a significant decrease in the incidence of dental caries.

Multivitamin with Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet. Because the tablets are chewable, they provide a *topical* as well as *systemic* source of fluoride.

Hydroxyapatite is the principal crystal for all calcified tissue in the human body. The fluoride ion reacts with the *hydroxyapatite* in the tooth as it is formed to produce the more caries-resistant crystal, *fluorapatite*. The reaction may be expressed by the equation:



Three stages of fluoride deposition in tooth enamel can be distinguished:

1. Small amounts (reflecting the low levels of fluoride in tissue fluids) are incorporated into the enamel crystals while they are being formed.
2. After enamel has been laid down, fluoride deposition continues in the surface enamel. Diffusion of fluoride from the surface inward is apparently restricted.
3. After eruption, the surface enamel acquires fluoride from the water, food, supplementary fluoride and smaller amounts from saliva.

INDICATIONS AND USAGE

Supplementation of the diet with ten essential vitamins.

Supplementation of the diet with fluoride for caries prophylaxis.

Multivitamin with 1 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 6-16 years of age in areas where the water fluoride level is less than 0.3 ppm.

Multivitamin with 0.5 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the water fluoride level is less than 0.3 ppm, and for children 6 years of age and above where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with 0.25 mg Fluoride Chewable Tablets provide fluoride in tablet form for children 4-6 years of age where the drinking water contains 0.3 through 0.6 ppm of fluoride.

Multivitamin with Fluoride Chewable Tablets supply significant amounts of Vitamins A, C, D, E, thiamin, riboflavin, niacin, vitamin B6, vitamin B12, and folate to supplement the diet, and to help assure that nutritional deficiencies of these vitamins will not develop. Thus, in a single easy-to-use preparation, children obtain ten essential vitamins and the important mineral, fluoride.

The American Academy of Pediatrics recommends that children up to age 16, in areas where drinking water contains less than optimal levels of fluoride, receive daily fluoride supplementation.

Children using Multivitamin with Fluoride Chewable Tablets regularly should receive semiannual dental examinations. The regular brushing of teeth and attention to good oral hygiene practices are also essential.

WARNING

As in the case of all medications, keep out of the reach of children.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking.

PRECAUTIONS

The suggested dose of Multivitamin with Fluoride Chewable Tablets *should not be exceeded*, since dental fluorosis may result from continued ingestion of large amounts of fluoride.

Before prescribing Multivitamin with Fluoride Chewable Tablets:

1. Determine the fluoride content of the drinking water from all major sources.
2. Make sure the child is not receiving significant amounts of fluoride from other sources such as medications and swallowed toothpaste.
3. Periodically check to make sure that the child does not develop significant dental fluorosis.

Do not eat or drink dairy products within one hour of medication administration.

ADVERSE REACTIONS

Allergic rash and other idiosyncrasies have been rarely reported.

DOSAGE AND ADMINISTRATION

One tablet daily or as prescribed.

HOW SUPPLIED

Multi-vitamin with Fluoride Chewable Tablets Grape are available as follows:

- 1 mg: Bottles of 100: NDC 0603-4383-21
Bottles of 500: NDC 0603-4383-28
- 0.5 mg: Bottles of 100: NDC 0603-4382-21
Bottles of 500: NDC 0603-4382-28
- 0.25 mg: Bottles of 100: NDC 0603-4381-21
Bottles of 500: NDC 0603-4381-28

Manufactured for:

QUALITEST PHARMACEUTICALS

130 Vintage Drive
Huntsville, AL 35811

8183001
R10/12-R3

PRINCIPAL DISPLAY PANEL

NDC 0603-4381-21

MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE

0.25 mg

MULTIVITAMIN AND FLUORIDE SUPPLEMENT

Rx only

100 TABLETS

Qualitest

Nutrition Facts	
Amount Per Tablet	% Daily Value Adults & Children 4 Years or More
Vitamin A	2500 IU 50%
Vitamin C	50 mg 100%
Vitamin D	400 IU 100%
Vitamin E	15 IU 50%
Thiamin	1.05 mg 70%
Riboflavin	1.2 mg 70%
Niacin	13.5 mg 68%
Vitamin B6	1.05 mg 53%
Folate	0.3 mg 75%
Vitamin B12	4.5 mcg 75%
Fluoride	0.25 mg *

* Daily Value not established

WARNING: Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center Immediately.

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking. See package insert for dosage information and complete listing of ingredients.

Active Ingredient for caries prophylaxis:
Fluoride as sodium fluoride.

Manufactured for:
QUALITEST PHARMACEUTICALS
130 VINTAGE DRIVE
HUNTSVILLE, AL 35811
Rev. 5/09 RD
8082988 4381

non
varn


3 0603-4381-21 5

PRINCIPAL DISPLAY PANEL

NDC 0603-4382-21
MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE
0.5 mg
MULTIVITAMIN AND FLUORIDE SUPPLEMENT
Rx only
100 TABLETS

Qualitest[®]

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking. See package insert for dosage information and complete listing of ingredients.

Active Ingredient for caries prophylaxis:
 Fluoride as sodium fluoride.

Manufactured for:
QUALITEST PHARMACEUTICALS
 130 VINTAGE DRIVE
 HUNTSVILLE, AL 35811
 Rev. 5/09 R0
 8082999 4382

non varn

N 3 0603-4382-21 2

Nutrition Facts
 Dosage Size 1 Chewable Tablet

Amount Per Tablet	% Daily Value Adults & Children 4 Years or More
Vitamin A	2500 IU 50%
Vitamin C	60 mg 100%
Vitamin D	400 IU 100%
Vitamin E	15 IU 50%
Thiamin	1.05 mg 70%
Riboflavin	1.2 mg 70%
Niacin	13.5 mg 68%
Vitamin B6	1.05 mg 53%
Folate	0.3 mg 75%
Vitamin B12	4.5 mcg 75%*
Fluoride	0.5 mg

* Daily Value not established

WARNING: Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center Immediately.

PRINCIPAL DISPLAY PANEL

NDC 0603-4383-21
MULTI-VITAMIN WITH FLUORIDE CHEWABLE TABLETS GRAPE
1 mg
MULTIVITAMIN AND FLUORIDE SUPPLEMENT
Rx only
100 TABLETS

Qualitest[®]

Should be chewed. This product, as all chewable tablets, is not recommended for children under age 4 due to risk of choking. See package insert for dosage information and complete listing of ingredients.

Active Ingredient for caries prophylaxis:
 Fluoride as sodium fluoride.

Manufactured for:
QUALITEST PHARMACEUTICALS
 130 VINTAGE DRIVE
 HUNTSVILLE, AL 35811
 Rev. 9/09 R1
 8083000 4383

non varn

N 3 0603-4383-21 9

Nutrition Facts
 Dosage Size 1 Chewable Tablet

Amount Per Tablet	% Daily Value Adults & Children 4 Years or More
Vitamin A	2500 IU 50%
Vitamin C	60 mg 100%
Vitamin D	400 IU 100%
Vitamin E	15 IU 50%
Thiamin	1.05 mg 70%
Riboflavin	1.2 mg 70%
Niacin	13.5 mg 68%
Vitamin B6	1.05 mg 53%
Folate	0.3 mg 75%
Vitamin B12	4.5 mcg 75%*
Fluoride	1 mg

* Daily Value not established

WARNING: Keep out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center Immediately.

MULTI VITAMIN WITH FLUORIDE

multi vitamin with fluoride tablet, chewable

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0603-4381
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.25 mg	
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A ACETATE	2500 [iU]	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg	

SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	SODIUM ASCORBATE	36 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL ACETATE, DL-	15 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE MONONITRATE	1.05 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.3 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR (UNII: 8M707QY5GH)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	4378;V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-4381-21	100 in 1 BOTTLE, PLASTIC		
2	NDC:0603-4381-28	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/09/2009	

MULTI VITAMIN WITH FLUORIDE

multi vitamin with fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0603-4382
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.5 mg
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A ACETATE	2500 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	SODIUM ASCORBATE	36 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL ACETATE, DL-	15 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE MONONITRATE	1.05 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.3 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR (UNII: 8M707QY5GH)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	SQUARE	Size	13mm
Flavor	GRAPE	Imprint Code	4379;V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-4382-21	100 in 1 BOTTLE, PLASTIC		
2	NDC:0603-4382-28	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/09/2009	

MULTI VITAMIN WITH FLUORIDE

multi vitamin with fluoride tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0603-4383
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1 mg
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A ACETATE	2500 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
SODIUM ASCORBATE (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	SODIUM ASCORBATE	36 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	400 [iU]
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL ACETATE, DL-	15 [iU]
THIAMINE MONONITRATE (UNII: 8K0I04919X) (Thiamine ION - UNII:4ABT0J945J)	THIAMINE MONONITRATE	1.05 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	1.05 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.3 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

Inactive Ingredients

Ingredient Name	Strength
RAW SUGAR (UNII: 8M707QY5GH)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	ROUND	Size	13mm
Flavor	GRAPE	Imprint Code	4380;V
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0603-4383-21	100 in 1 BOTTLE, PLASTIC		

2 | NDC:0603-4383-28

500 in 1 BOTTLE, PLASTIC

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/09/2009	

Labeler - Qualitest Pharmaceuticals (011103059)

Establishment

Name	Address	ID/FEI	Business Operations
Vintage Pharmaceuticals-Huntsville		825839835	MANUFACTURE(0603-4381, 0603-4382, 0603-4383)

Revised: 11/2012

Qualitest Pharmaceuticals