

**MULTIVITAMIN WITH FLUORIDE- sodium fluoride tablet, chewable  
WINDER LABORATORIES, 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.*

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**MULTIVITAMIN WITH FLUORIDE CHEWABLE TABLETS  
0.25 mg, 0.5 mg and 1.0 mg**

**Prescribing Information**

**Rx Only**

<b>Nutrition Facts</b>				
<b>Serving Size 1 Chewable Tablet</b>				
<b>Serving Per Container 100</b>				
<b>Amount Per Serving (1 Chewable Tablet)</b>	<b>1.0 mg</b>	<b>0.5 mg</b>	<b>0.25 mg</b>	<b>% DV Adults &amp; Children 4 Years or More</b>
Vitamin A (as Retinyl acetate)	750 mcg RAE	750 mcg RAE	750 mcg RAE	83%
Vitamin C (Sodium Ascorbate 36 mg/ Ascorbic Acid 24 mg)	60 mg	60 mg	60 mg	67%
Vitamin D	10 mcg	10 mcg	10 mcg	50%
Vitamin E (as dl-alpha-tocopherol acetate)	6.75 mg (15 IU)	6.75 mg (15 IU)	6.75 mg (15 IU)	45%
Thiamine.	1.05 mg	1.05 mg	1.05 mg	88%
Riboflavin	1.2 mg	1.2 mg	1.2 mg	92%
Niacin	13.5 mg	13.5 mg	13.5 mg	84%
Vitamin B6	1.05 mg	1.05 mg	1.05 mg	62%
Folate	0.5 mg.	0.5 mg.	0.5 mg	125%
Vitamin B12	4.5 mcg	4.5 mcg	4.5 mcg	188%
Fluorid	1.0 mg	0.5 mg	0.25 mg	*

\* Daily Value (% DV) not established

Active ingredients:

Fluoride as sodium fluoride.

Other Ingredients:

Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose.

0.25 mg also contains: D&C Red #27 Alum Lake and FD&C Yellow #6 Alum Lake.

0.5 mg also contains: FD&C Red #40 Alum Lake.

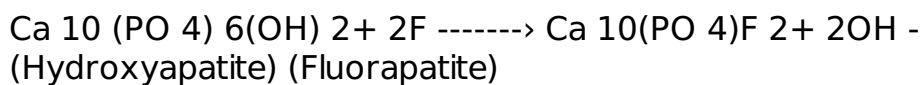
1.0 mg also contains: D&C Red #27 and FD&C Blue #1.

## 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:



(Hydroxyapatite) (Fluorapatite)

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 fluoride and ten essential vitamins.

**Multivitamin with 1.0 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, thiamine, 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.

Supplementation of the diet with fluoride for caries prophylaxis.

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.

**Multivitamin with Fluoride Chewable tablets** are prescription product for the clinical dietary management of metabolic processes of caries prophylaxis and provides supplementation of the diet with ten essential vitamins.

## **WARNING**

**Keep this and all medication out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.**

**Keep this and all medication out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.**

## **CAUTION**

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

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

## **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.

## **ADVERSE REACTIONS**

Allergic rash and other idiosyncrasies have been rarely reported.

## **DOSAGE AND ADMINISTRATION**

One tablet daily or as prescribed.

## HOW SUPPLIED

3.25 mg: Multivitamin chewable tablets containing 0.25 mg fluoride are pink-colored, grape flavor, un-scored, round tablet, debossed with "WL" "169" on one side and plain on other side of tablet. Available in bottle of 100 (NDC 75826-169-10).

0.5 mg: Multivitamin chewable tablets containing 0.5 mg fluoride are peach-colored, grape flavor, un-scored, round tablet, debossed with "WL" "170" on one side and plain on other side of tablet. Available in bottle of 100 (NDC 75826-170-10).

1.0 mg: Multivitamin chewable tablets containing 1.0 mg fluoride are purple-colored, grape flavor, un-scored, round tablet, debossed with "WL" "171" on one side and plain on other side of tablet. Available in bottle of 100 (NDC 75826-171-10).

## STORAGE

Store at 20° - 25°C (68°-77°F); excursions permitted to 15° - 30°C (59°-86°F). See USP Controlled Room Temperature.

Dispense in a tight, light resistant container with a child-resistant closure as defined in the USP/NF. All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

**Manufactured by:**  
**Winder Laboratories LLC**  
**Winder GA, 30680**

**RLS.170.99-3.0**  
**Rev: 01/2024**

## Package/Label Display Panel

.7086" w x 1.5748" h	Each Chewable Tablet Contains:		Multivitamin with Fluoride 0.25 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride.	NDC 75826-169-10	Rx Only	
	<b>Supplement Facts</b>		Multivitamin with Fluoride 0.25 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.	<b>Multivitamin with Fluoride</b> Chewable Tablets <b>0.25 mg</b> Grape Flavor Manufactured by: <b>WINDER LABORATORIES LLC</b> Winder, GA 30680 <b>winder</b> LABS <b>100 TABLETS</b>		
	Serving Size:	1 Chewable Tablet	<b>Other Ingredients:</b> Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose, FD&C Yellow No.6 Alum Lake, D&C Red No.27 Alum Lake.  Consult Package Insert For Full Prescribing Information.  Part # RLS.169.10-3.0 Jan 2024			
	Servings per container:	100				
	Amount Per Serving					
		%DV Adults and Children 4 years or More				
	Vitamin A (as Retinyl Acetate)	750 mcg RAE				83%
	Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)	60 mg				67%
	Vitamin D (as Cholecalciferol)	10 mcg				50%
	Vitamin E (as dl-alpha-tocopherol acetate)	6.75 mg (15 IU)				45%
Thiamine (as Thiamine Mononitrate)	1.05 mg	88%				
Riboflavin (as Vit B2)	1.2 mg	92%				
Niacin (as Niacinamide)	13.5 mg	84%				
Vitamin B6 (as Pyridoxine Hydrochloride)	1.05 mg	62%				
Folate (as Folic Acid) 500 mcg DFE (300 mcg Folic Acid)		125%				
Vitamin B12 (as Cyanocobalamin)	4.5 mcg	188%				
Fluoride	0.25 mg	*				
* Daily Value (DV) not established						

Each Chewable Tablet Contains:

Supplement Facts		
Serving Size:	1 Chewable Tablet	
Servings per container:	100	
Amount Per Serving		%DV Adults and Children 4 years or More
Vitamin A (as Retinyl Acetate)	750 mcg RAE	83%
Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)	60 mg	67%
Vitamin D (as Cholecalciferol)	10 mcg	50%
Vitamin E (as dl-alpha-tocopherol acetate)	6.75 mg (15 IU)	45%
Thiamine (as Thiamine Mononitrate)	1.05 mg	88%
Riboflavin (as Vit B2)	1.2 mg	92%
Niacin (as Niacinamide)	13.5 mg	84%
Vitamin B <sub>6</sub> (as Pyridoxine Hydrochloride)	1.05 mg	62%
Folate (as Folic Acid) 500 mcg DFE (300 mcg Folic Acid)	4.5 mcg	125%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	4.5 mcg	188%
Fluoride	0.5 mg	*

\* Daily Value (DV) not established

Multivitamin with Fluoride 0.5 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Multivitamin with Fluoride 0.5 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

Other Ingredients: Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose, FD&C Red #40 Alum Lake 14-16%.

Consult Package Insert For Full Prescribing Information.

Part # RLS.170.10-3.0 Jan 2024



NDC 75826-170-10

Rx Only

Multivitamin with Fluoride Chewable Tablets

0.5 mg

Grape Flavor

Manufactured by:  
WINDER LABORATORIES LLC  
Winder, GA 30680

winder LABS

100 TABLETS

.7086" w x 1.5748" h

Each Chewable Tablet Contains:

Supplement Facts		
Serving Size:	1 Chewable Tablet	
Servings per container:	100	
Amount Per Serving		%DV Adults and Children 4 years or More
Vitamin A (as Retinyl Acetate)	750 mcg RAE	83%
Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)	60 mg	67%
Vitamin D (as Cholecalciferol)	10 mcg	50%
Vitamin E (as dl-alpha-tocopherol acetate)	6.75 mg (15 IU)	45%
Thiamine (as Thiamine Mononitrate)	1.05 mg	88%
Riboflavin (as Vit B2)	1.2 mg	92%
Niacin (as Niacinamide)	13.5 mg	84%
Vitamin B <sub>6</sub> (as Pyridoxine Hydrochloride)	1.05 mg	62%
Folate (as Folic Acid) 500 mcg DFE (300 mcg Folic Acid)	4.5 mcg	125%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	4.5 mcg	188%
Fluoride	1 mg	*

\* Daily Value (DV) not established

Multivitamin with Fluoride 1.0 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Multivitamin with Fluoride 1.0 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

Other Ingredients: Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose, D&C Red No.27, FD&C BLUE NO.1.

Consult Package Insert For Full Prescribing Information.

Part # RLS.171.10-3.0 Jan 2024



NDC 75826-171-10

Rx Only

Multivitamin with Fluoride Chewable Tablets

1.0 mg

Grape Flavor

Manufactured by:  
WINDER LABORATORIES LLC  
Winder, GA 30680

winder LABS

100 TABLETS

.7086" w x 1.5748" h

## MULTIVITAMIN WITH FLUORIDE

sodium fluoride tablet, chewable

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75826-170
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.5 mg
<b>VITAMIN A</b> (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WP17EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg

<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

### Inactive Ingredients

Ingredient Name	Strength
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	red (Peach colored)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	GRAPE (Grape flavor)	<b>Imprint Code</b>	WL170
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-170-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2023	

.7086" w x 1.5748" h

Each Chewable Tablet Contains:

Supplement Facts		
Amount Per Serving		%DV Adults and Children 4 years or More
Vitamin A (as Retinyl Acetate)	750 mcg RAE	50%
Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)	60 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg	100%
Vitamin E	13.5 mg	50%
Thiamin (as Thiamine Mononitrate)	1.05 mg	70%
Riboflavin (as Vit B2)	1.2 mg	71%
Niacin (as Niacinamide)	13.5 mg	68%
Vitamin B6 (as Pyridoxine Hydrochloride)	1.05 mg	53%
Folate (as Folic Acid) 500 mcg DFE (300 mcg Folic Acid)	4.5 mcg	75%
Vitamin B12 (as Cyanocobalamin)	4.5 mcg	75%
Fluoride	0.5 mg	*

\* Daily Value (DV) not established

Multivitamin with Fluoride 0.5 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Multivitamin with Fluoride 0.5 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

**Other Ingredients:** Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose, FD&C Red #40 Alum Lake 14-16%.

Consult Package Insert For Full Prescribing Information.

Part # RLS.170.10-1.0  
Aug 2023

NDC 75826-170-10 Rx Only

Multivitamin with Fluoride Chewable Tablets

**0.5 mg**

Grape Flavor

Manufactured by:  
**WINDER LABORATORIES LLC**  
Winder, GA 30680

**winder**  
LABS

**100 TABLETS**

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2023	

## MULTIVITAMIN WITH FLUORIDE

sodium fluoride tablet, chewable

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:75826-169
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg
<b>VITAMIN A</b> (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

## Inactive Ingredients

Ingredient Name	Strength
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

## Product Characteristics

<b>Color</b>	pink (Pink Colored)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	WL169
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-169-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2024	



Each Chewable Tablet Contains:

**Supplement Facts**

Serving Size:	1 Chewable Tablet	
Servings per container:	100	
Amount Per Serving	%DV Adults and Children 4 years or More	
Vitamin A (as Retinyl Acetate)	750 mcg RAE	50%
Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)	60 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg	100%
Vitamin E	13.5 mg	50%
Thiamin (as Thiamine Mononitrate)	1.05 mg	70%
Riboflavin (as Vit B2)	1.2 mg	71%
Niacin (as Niacinamide)	13.5 mg	68%
Vitamin B6 (as Pyridoxine Hydrochloride)	1.05 mg	53%
Folate (as Folic Acid) 500 mcg DFE (300 mcg Folic Acid)		75%
Vitamin B12 (as Cyanocobalamin)	4.5 mcg	75%
Fluoride	0.25 mg	*

\* Daily Value (DV) not established

Multivitamin with Fluoride 0.25 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Multivitamin with Fluoride 0.25 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

**Other Ingredients:** Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose, FD&C Yellow No.6 Alum Lake, D&C Red No.27 Alum Lake.

Consult Package Insert For Full Prescribing Information.

Part # RLS.169.10-1.0  
Aug 2023



NDC 75826-169-10

Rx Only

Multivitamin with Fluoride  
Chewable Tablets

**0.25 mg**

Grape Flavor

Manufactured by:  
WINDER LABORATORIES LLC  
Winder, GA 30680

**winder**  
LABS

100 TABLETS

.7086" w x 1.5748" h

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2023	

**MULTIVITAMIN WITH FLUORIDE**

sodium fluoride tablet, chewable

**Product Information**

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:75826-171
Route of Administration	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg
<b>VITAMIN A</b> (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	750 ug
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	24 mg
<b>SODIUM ASCORBATE</b> (UNII: S033EH8359) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	36 mg
<b>CHOLECALCIFEROL</b> (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	10 ug
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	6.75 mg
<b>THIAMINE MONONITRATE</b> (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.05 mg
<b>RIBOFLAVIN</b> (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	1.2 mg
<b>NIACINAMIDE</b> (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	13.5 mg
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	1.05 mg
<b>FOLIC ACID</b> (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	4.5 ug

**Inactive Ingredients**

Ingredient Name	Strength
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<b>SUCROSE</b> (UNII: C151H8M554)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>D&amp;C RED NO. 27</b> (UNII: 2LRS185U6K)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE 102</b> (UNII: PNR0YF693Y)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>FD&amp;C BLUE NO. 1 ALUMINUM LAKE</b> (UNII: J9EQA3S2JM)	

### Product Characteristics

<b>Color</b>	purple (Purple colored)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	13mm
<b>Flavor</b>	GRAPE (Grape flavor)	<b>Imprint Code</b>	WL171
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-171-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/01/2023	

.7086" w x 1.5748" h

**Each Chewable Tablet Contains:**

**Supplement Facts**

Serving Size: 1 Chewable Tablet  
Servings per container: 100

Amount Per Serving		%DV Adults and Children 4 years or More
Vitamin A (as Retinyl Acetate)	750 mcg RAE	50%
Vitamin C (as Sodium Ascorbate 36 mg / Ascorbic Acid 24 mg)	60 mg	100%
Vitamin D (as Cholecalciferol)	10 mcg	100%
Vitamin E	13.5 mg	50%
Thiamin (as Thiamine Mononitrate)	1.05 mg	70%
Riboflavin (as Vit B2)	1.2 mg	71%
Niacin (as Niacinamide)	13.5 mg	68%
Vitamin B <sub>6</sub> (as Pyridoxine Hydrochloride)	1.05 mg	53%
Folate (as Folic Acid) 500 mcg DFE (300 mcg Folic Acid)		75%
Vitamin B <sub>12</sub> (as Cyanocobalamin)	4.5 mcg	75%
Fluoride	1 mg	*

\* Daily Value (DV) not established

Multivitamin with Fluoride 1.0 mg active ingredient for caries prophylaxis: Fluoride as sodium fluoride.

Multivitamin with Fluoride 1.0 mg Fluoride Chewable Tablets provide sodium fluoride and ten essential vitamins in a chewable tablet.

**Other Ingredients:** Croscarmellose Sodium, Grape Flavor, Magnesium Stearate, Microcrystalline Cellulose, Stearic Acid, Sucrose, D&C Red No.27, FD&C BLUE NO.1.

Consult Package Insert For Full Prescribing Information.

Part # RLS.171.10-1.0  
Aug 2023

NDC 75826-171-10 Rx Only

**Multivitamin with Fluoride**

Chewable Tablets

**1.0 mg**

Grape Flavor

Manufactured by:  
**WINDER LABORATORIES LLC**  
Winder, GA 30680

winder

LABS

100 TABLETS

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/2023	

**Labeler** - WINDER LABORATORIES, LLC (965195170)

### Establishment

Name	Address	ID/FEI	Business Operations
WINDER LABORATORIES, LLC		965195170	manufacture(75826-169, 75826-170, 75826-171)

