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.

Sodium Fluoride Chewable Tablets

This insert is for 1.0 mg strength tablets, 0.5 mg strength tablets, and 0.25 mg strength tablets.

Rx Only

This product is a prescription product for the clinical dietary management of the metabolic processes of caries prophylaxis.

120 Tablets per bottle

Water F^- Content			
Ages	**0 ppm F^- to <0.3 ppm F^-**	**0.3 ppm F^- to 0.6ppm F^-**	**>0.6ppm F^-**
3 yrs. to 6 yrs.	0.5mg*	0.25mg*	0
>6yrs. to 16 yrs.	1.0mg*	0.5mg*	0

* Per day

Active Ingredient: Fluoride (as Sodium Fluoride)

0.25 mg / 0.5 mg / 1.0 mg

Inactive Ingredients: Microcrystalline cellulose, D-Mannitol, Sucrose, Stearic acid, Magnesium stearate, Natural Grape flavor.

0.25mg 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

Sodium Fluoride acts systemically (before tooth eruption) and topically (post-eruption) by increasing tooth resistance to acid dissolution, by promoting remineralization, and by inhibiting the cariogenic microbial process.

INDICATIONS AND USAGE

For once daily self-applied systemic use as a dental caries preventive in pediatric patients. It has been established that ingestion of fluoridated drinking water (1 ppm F^-)

during the period of tooth development results in a significant decrease in the incidence of dental caries. Sodium Fluoride Chewable Tablets were developed to provide systemic fluoride for use as a supplement in pediatric patients from age 3 years to age 16 years and older living in areas where the drinking water fluoride contents does not exceed 0.6 ppm F^-.

CONTRAINDICATIONS

Fluoride 1.0 mg Tablets are contraindicated when the fluoride content of drinking water is >0.3 ppm F^- and should not be administered to pediatric patients under 6 years.

Fluoride 0.5 mg Tablets are contraindicated when the fluoride content of drinking water is more than 0.6 ppm F^- and should not be administered to pediatric patients under age 6 when the fluoride content of drinking water is 0.3 ppm F^- or more or to pediatric patients under age 3 years.

Fluoride 0.25 mg Tablets are contraindicated when the fluoride content of drinking water is more than 0.6 ppm F^- and should not be administered to pediatric patients under age 3 years when the fluoride content of drinking water is 0.3 ppm F^- or more. Do not administer Sodium Fluoride Chewable Tablets (any strength) to pediatric patients under age 3 years. Sodium Fluoride Chewable Tablets (any strength) are not indicated for use in adults.

OVERDOSAGE

Accidental ingestion of large amounts of fluoride may result in acute burning in the mouth and sore tongue. Nausea, vomiting, and diarrhea may occur soon after ingestion (within 30 minutes) and are accompanied by salivation, hematemesis, and epigastric cramping abdominal pain. These symptoms may persist for 24 hours. If less than 5 mg fluoride/kg body weight (i.e., less than 2.3 mg fluoride/lb body weight) have been ingested, give calcium (e.g., milk) orally to relieve gastrointestinal symptoms and observe for a few hours. If more than 5 mg fluoride/kg body weight (i.e., more than 2.3 mg fluoride/lb body weight) have been ingested, induce vomiting, give orally soluble calcium (e.g., milk, 5% calcium gluconate or calcium lactate solution) and immediately seek medical assistance. For accidental ingestion of more than 15 mg fluoride/kg body weight (i.e., more than 6.9 mg fluoride/lb body weight), induce vomiting and admit immediately to a hospital facility.

A bottle of 120 0.25 mg tablets contains 30 mg fluoride. A bottle of 120 0.5 mg tablets contains 60 mg fluoride. A bottle of 120 1 mg tablets contains 120 mg fluoride. [The total amount of sodium fluoride in a bottle of 120 Fluoride Chewable Tablets (all strengths) conforms with the recommended amount of the American Dental Association for the maximum to be dispensed at one time for safety purposes.]

WARNING

Prolonged daily ingestion of quantities greater than the recommended amount may result in various degrees of dental fluorosis in pediatric patients under age 6 years, especially if the water fluoridation exceeds 0.6 ppm. Read directions carefully before using. This product, as all chewable tablets, is not recommended for children under age

3 due to risk of choking.

Keep out of the reach of infants and children.

PRECAUTIONS

General

Please refer to the **CONTRAINDICATIONS,WARNINGS**and **OVERDOSAGE**sections for overdosage concerns. Use in pediatric patients below the age of 3 years is not recommended by current American Dental Associations and American Academy of Pediatrics guidelines.

Drug Interactions:

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.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a study conducted in rodents, no carcinogenesis was found in male and female rats treated with fluoride at dose levels ranging from 4.1 to 9.1 mg/kg of body weight. Equivocal evidence of carcinogenesis was reported for male rats treated with 2.5 and 4.1 mg/kg of body weight. In a second study, no carcinogenesis was observed in rats, males or females, treated with fluoride up to 11.3 mg/kg of body weight. This dose is at least 400 times greater than the recommended daily dose of Sodium Fluoride Chewable Tablets. Fluoride ion is not mutagenic in standard bacterial systems. It has been shown that fluoride ion has potential to induce chromosome aberrations in cultured human and rodentcells at does much higher than those to which humans are exposed. In vivo data is conflicting. Some studies report chromosome damage in rodents while other studies using similar protocols report negative results. Potential adverse reproductive effects of fluoride exposure in humans has not been adequately evaluated. Adverse effects on reproduction were reported for rats, mice, fox, and cattle exposed to 100 ppm or greater concentrations of fluoride in their diet or drinking water. Other studies conducted in rats demonstrated that lower doses of fluoride (5 mg/kg of body weight) did not result in impaired fertility and reproductive capabilities. This dose is approximately 200 times greater than the recommended daily dose of Sodium Fluoride Chewable Tablets.

Pregnancy

Teratogenic Effects

Pregnancy Category B

It has been shown that fluoride crosses the placenta of rats, but only 0.01% of the amount administered is incorporated in fetal tissue. Animal studies (rats, mice, rabbits) have shown that fluoride is not a teratogen. Maternal exposure to 12.2 mg fluoride/kg of body weight (rats) or 13.1 mg/kg of body weight (rabbits) did not affect the litter size or fetal weight and did not increase the frequency of skeletal or visceral malformations. Epidemiological studies conducted in areas with high levels of naturally fluoridated water

showed no increase in birth defects. Heavy exposure to fluoride during in utero development may result in skeletal fluorosis which becomes evident in childhood.

Nursing Mothers

It is not known if fluoride is excreted in human milk. However, many drugs are excreted in human milk and caution should be exercised when Sodium Fluoride Chewable Tablets are administered to a nursing woman. Reduced milk production was reported in farm raised fox when the animals were fed a diet containing a high concentration of fluoride (98-137 mg/kg of body weight). No adverse effects on parturition, lactation, or offspring were seen in rats administered fluoride up to 5 mg/kg of body weight. This dose is at least 200 times greater than the recommended daily dose of Sodium Fluoride Chewable Tablets.

Geriatric Use

Sodium Fluoride Chewable Tablets (any strength) are not indicated for use in geriatric patients.

Pediatric Use

The use of Sodium Fluoride Chewable Tablets as a caries preventive in pediatric age groups 3 years to 16 years is supported by evidence from adequate and well controlled studies on fluoride supplementation from birth through adolescence.

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 to the FDA at 1(800) FDA-1088.

DOSAGE AND ADMINISTRATION

(for dosage see table)

Dissolve in the mouth or chew before swallowing, preferably at bedtime after brushing teeth. See schedule below to determine dosage.

HOW SUPPLIED

120 count Chewable tablets

Each tablet contains 0.25 mg Fluoride from 0.55 mg Sodium Fluoride. Pink-colored, grape flavor, un-scored, round chewable tablet, debossed with "WL" "163" on one side and plain on other side of tablet. NDC 75826-163-20 (120 count).

Each tablet contains 0.5 mg Fluoride from 1.1 mg Sodium Fluoride. Peach-colored, grape flavor, un-scored, round chewable tablet, debossed with “WL" "164” on one side and plain on other side of tablet. NDC 75826-164-20 (120 count).

Each tablet contains 1.0 mg Fluoride from 2.2 mg Sodium Fluoride. Purple-colored, grape flavor, un-scored, round chewable tablet, debossed with “WL” “165” on one side

and plain on other side of tablet. NDC 75826-165-20 (120 count).

STORAGE

Store at 25° C (77° F); excursions permitted to 15° - 30° C (59° - 86° F). See USP Controlled Room Temperature. Protect from light and moisture.

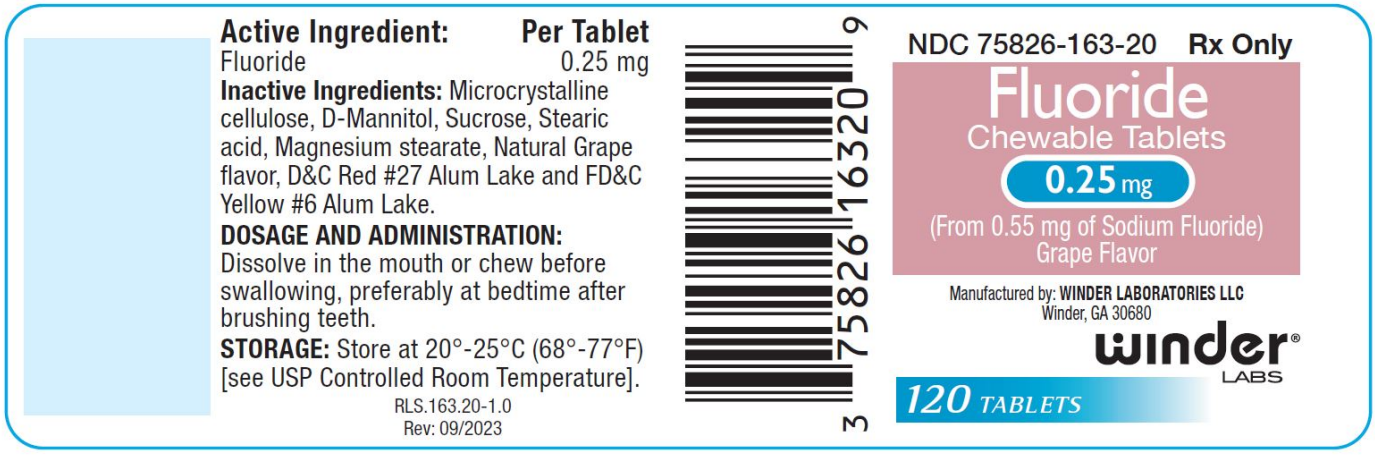
Dispense in a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

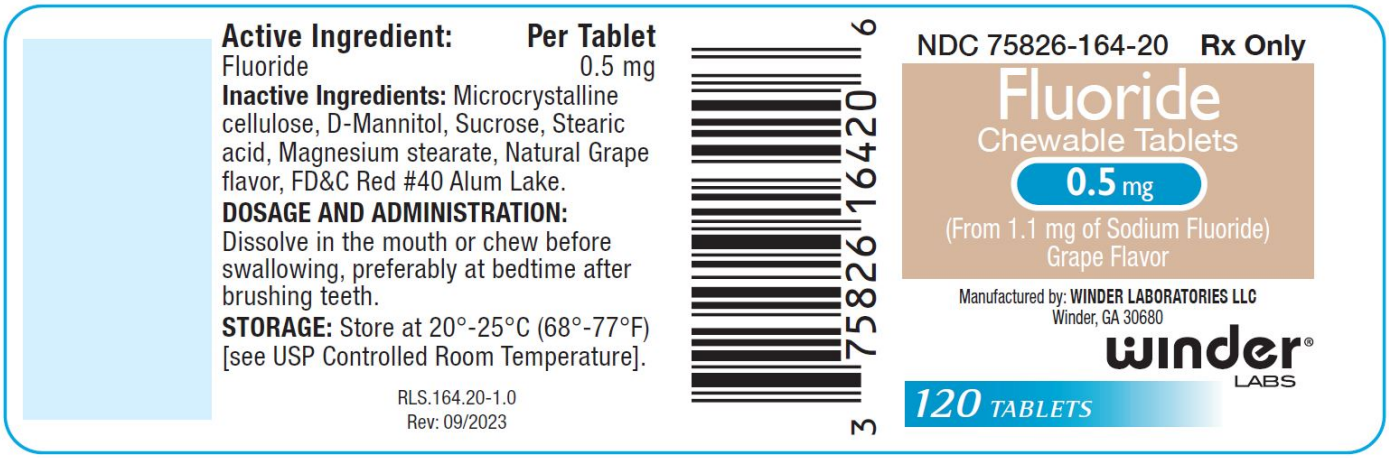
Warning: Keep this and all medications out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

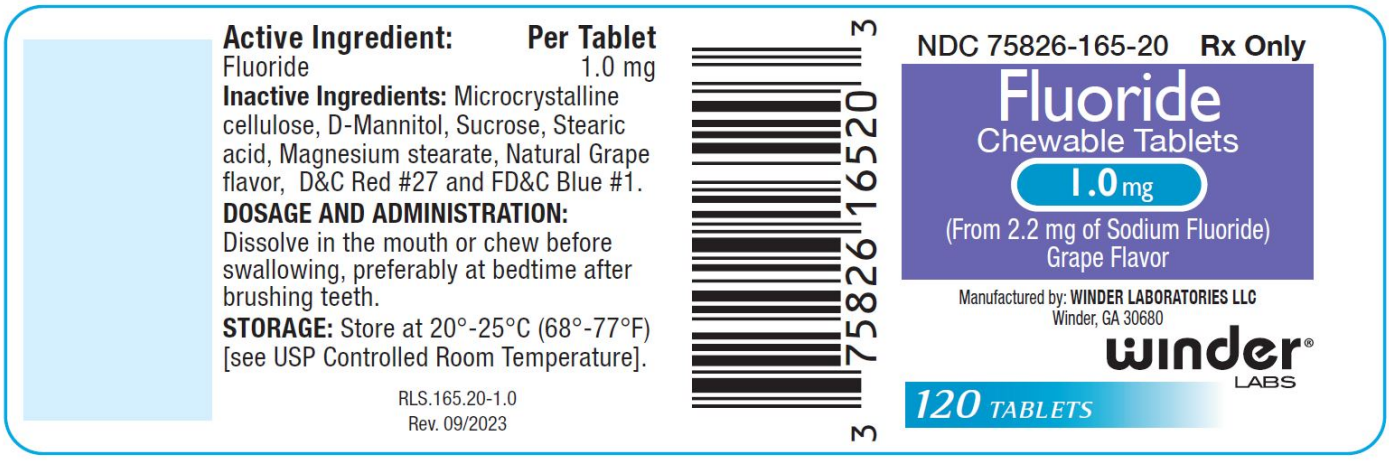
Manufactured by:
Winder Laboratories LLC
Winder GA, 30680

RLS.164.99-1.0

Rev: 09/2023







FLUORIDE

sodium fluoride tablet, chewable

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75826-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SUCROSE (UNII: C151H8M554)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	

Product Characteristics			
Color	pink (Pink-Colored)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor	GRAPE (Natural Grape Flavor)	**Imprint Code**	WL163
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start**	**Marketing End**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-163-20	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2024	

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Product Information

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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)	FLUORIDE ION	0.5 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SUCROSE (UNII: C151H8M554)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics

Color	orange (Peach-Colored)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor	GRAPE (Natural Grape Flavor)	**Imprint Code**	WL164
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-164-20	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2024	

FLUORIDE

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Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:75826-165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE 102 (UNII: PNR0YF693Y)	
SUCROSE (UNII: C151H8M554)	
MANNITOL (UNII: 3OWL53L36A)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	

Product Characteristics

Color	purple (Purple-Colored)	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor	GRAPE (Natural Grape Flavor)	**Imprint Code**	WL165
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75826-165-20	120 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/2024	

Labeler - WINDER LABORATORIES, LLC (965195170)

Registrant - WINDER LABORATORIES, LLC (965195170)

Establishment

Name	Address	ID/FEI	Business Operations
WINDER LABORATORIES, LLC		965195170	manufacture(75826-163, 75826-164, 75826-165)

Revised: 1/2024 WINDER LABORATORIES, LLC