SODIUM FLUORIDE- sodium fluoride solution/ drops
Sancilio & Company Inc

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
Drops
0.5
mg/mL

GRAPE FLAVORED

Description

Each mL of Sodium Fluoride Drops contains 0.5 mg Fluoride ion (F) from 1.1 mg Sodium Fluoride (NaF). For use as a dental caries preventive in pediatric patients. No dyes, artificial flavors or sugar. Saccharin free. Gluten free.

Active Ingredients: Sodium Fluoride (0.11% w/v).

Other Ingredients: Glycerin, purified water, xylitol, propylene glycol, natural grape flavor, sucralose, methyl paraben, propyl paraben.

FLUORIDE SUPPLEMENT DOSAGE SCHEDULE§

AGE	Fluoride Ion Level in Drinking Water (ppm)*		
	< 0.3 ppm	**0.3 - 0.6 ppm**	**> 0.6 ppm**
Birth to 6 months	None	None	None
6 months to 3 years	Half dropperful 0.25 mg F (1/2 mL)	None	None
3 to 6 years	One dropperful 0.5 mg F (1 mL)†	Half dropperful 0.25 mg F (1/2 mL)	None
6 to 16 years	Two dropperfuls 1 mg F (2 mL)	One dropperful 0.5 mg F (1 mL)	None

* 1.0 ppm = 1 mg/Liter

† 1.1 mg Sodium Fluoride contains 0.5 mg Fluoride ion

Fluoride Supplement Dose Schedule approved by the American Dental Association, American Academy of Pediatrics and American Academy of Pediatric Dentistry.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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

As a supplemental source of Fluoride. It has been established that ingestion of fluoridated drinking water (1 ppm F) during the period of tooth development results in significant decrease in the incidence of dental caries.[1] Sodium Fluoride Drops were developed to provide systemic Fluoride for use as a supplement in pediatric patients from 6 months to age 3 and older, living in areas where the drinking water Fluoride level does not exceed 0.6 ppm F.

Contraindications

Do not use in areas where drinking water exceeds 0.6 ppm F. Do not administer to pediatric patients less than 6 months old.

Warnings

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. Keep out of the reach of infants and children.

Precautions

See "Overdosage" section. Incompatibility of Fluoride with dairy foods has been reported due to formation of Calcium Fluoride which is poorly absorbed. Not for use in the eyes.

Adverse Reactions

Allergic rash and other idiosyncrasies have been rarely reported.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or Sancilio & Company, Inc. at 1-800-SCI-0513.

Store at controlled room temperature 15° to 30°C (59° to 86°F).

TAMPER EVIDENT

Do not accept if printed bottle seal around cap is broken or missing.

Overdosage

Prolonged daily ingestion of excessive Fluoride may result in varying degrees of dental fluorosis. The total amount of Sodium Fluoride in a bottle of 50 mL (0.5 mg/mL) Sodium Fluoride Drops (25 mg F) conforms with the recommendations of the American Dental Association for the maximum to be dispensed at one time for safety purposes. If overdose is suspected, call 1-800-222-1222 (American Association of Poison Control Centers), your local poison control center (www.aapcc.org), or emergency room immediately for treatment recommendations.

Dosage§ and Administration

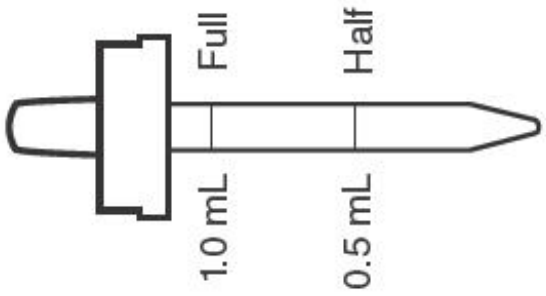
Daily oral dose: (in areas where the drinking water contains less than 0.3 ppm F) age 6 months to 3 years: one half dropperful (1/2 mL); age 3 to 6 years, one dropperful (1 mL); age 6 to 16 years, two dropperfuls (2 mL). When drinking water is partially fluoridated (0.3 to 0.6 ppm F inclusive) dose as follows: age 6 months to 3 years, Fluoride supplementation not indicated; age 3 to 6 years, one half dropperful (1/2 mL); age 6 to 16 years, one dropperful (1 mL).

How Supplied

50 mL bottles (44946-1032-8)

References

1. Accepted Dental Therapeutics, Ed. 40. American Dental Association, Chicago, 1984:399-402.
2. Jakush, J, New Fluoride Schedule Adopted. ADA News. May 16, 1994:12-14.



Lot No:

Exp Date:

Manufactured by: Sancilio & Company, Inc.
3874 Fiscal Court #200
Riviera Beach, FL 33404

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label

44946-1032-8

Sancilio & Company, Inc.
Developing Good Science into Great Medicine™

Sodium Fluoride
Drops
(Sodium Fluoride Oral Solution, USP)

0.5
mg/mL

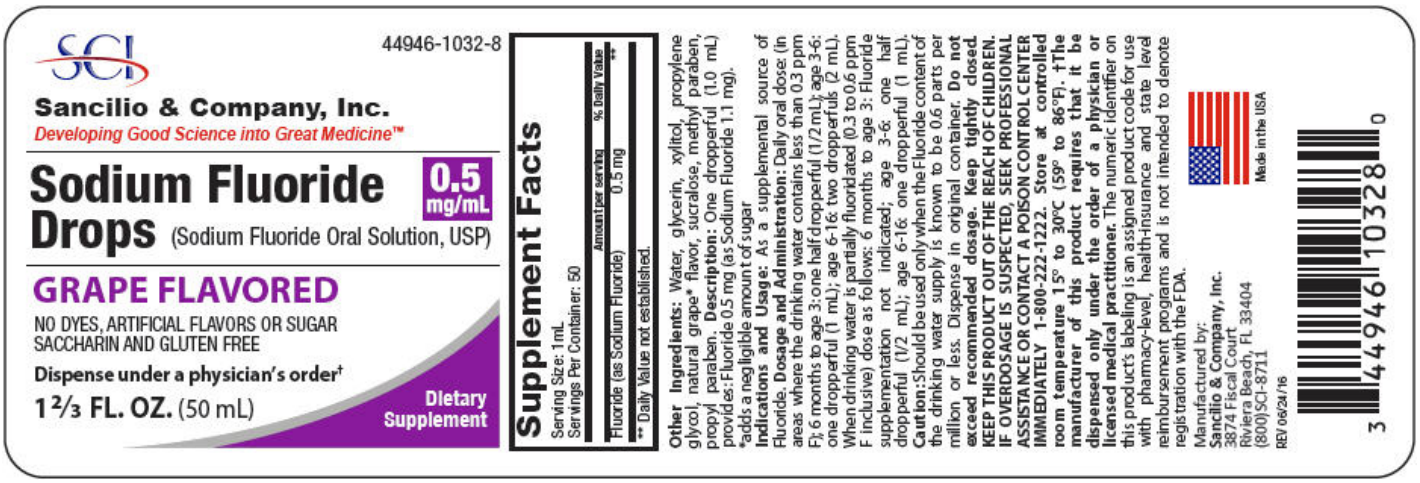
GRAPE FLAVORED

NO DYES, ARTIFICIAL FLAVORS OR SUGAR
SACCHARIN AND GLUTEN FREE

Dispense under a physician's order†

1 FL. OZ. (50 mL)

Dietary
Supplement



SODIUM FLUORIDE

sodium fluoride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:44946-1032
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 in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Xylitol (UNII: VCQ006KQ1E)	
Propylene glycol (UNII: 6DC9Q167V3)	
Sucralose (UNII: 96K6UQ3ZD4)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

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

1	NDC:44946-1032-8	50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	12/20/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/20/2011	

Labeler - Sancilio & Company Inc (176681257)

Revised: 5/2017 Sancilio & Company Inc