SODIUM FLUORIDE- sodium fluoride solution/ drops
Method Pharmaceuticals, 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 Drops

SODIUM FLUORIDE- sodium fluoride solution/ drops

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. Sugar Free, Alcohol Free, Dye Free and Gluten Free.

Supplement Facts

Serving Size: 1 mL

Servings Per Container: 50

Amount per serving	**% Daily Value**
Fluoride (as Sodium Fluoride) 0.5 mg	**

**** Daily Value not established.**

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

Other Ingredients: Glycerin, methylparaben, grape flavor, propylene glycol, purified water, sodium benzoate, sucralose.

FLUORIDE SUPPLEMENT DOSAGE SCHEDULES

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 Method Pharmaceuticals, LLC at 877-250-3427.

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

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.

Dosages 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 (58657-322-50)

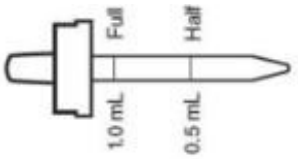
References

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.



Manufactured by:

Method Pharmaceuticals, LLC

Fort Worth, TX 76118

Rev. 07/2018

PRINCIPAL DISPLAY PANEL

NDC 58657-322-50

Sodium

Fluoride

Drops

Sodium Fluoride Oral Solution, USP

0.5 mg/mL

GRAPE FLAVORED

1.69 FL. OZ. (50 mL)

SODIUM FLUORIDE

sodium fluoride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58657-322
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)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58657-322-50	50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	08/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/15/2018	

Labeler - Method Pharmaceuticals, LLC (060216698)

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