SODIUM FLUORIDE DROPS- sodium fluoride solution/ drops
H2-Pharma, LLC

Sodium Fluoride Drops

Supplement Facts **Serving Size 1.0 mL** **Servings Per Container 50**		
	Amount Per Serving	**% Daily Value**
Fluoride	0.5 mg	*

* Daily Value not established

*U.S. Recommended Daily Allowance not established. Consult your physician for use by infants and children under 2 years of age.

Active Ingredient: Sodium fluoride 0.11% (w/v).

Other Ingredients: Citric acid, methyl paraben, peach flavor, purified water, red #33, sodium benzoate, sodium fluoride, sucralose, yellow #6.

These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

DOSAGE SCHEDULE* WATER F CONTENT

AGE	0-0.3 PPM	0.3-0.6 PPM	> 0.6 PPM
6 months to 3 years	0.25 mg F = 1/2 mL = Half dropperful	0	0
3-6 years	0.5 mg F = 1 mL = One dropperful	0.25 mg F = 1/2 mL = Half dropperful	0
6-16 years	1 mg F = 2 mL = Two dropperfuls	0.5 mg F = 1 mL = One dropperful	0

* Conforms to new ADA and AAP guidelines for supplementation.

Description

Each 1 mL contains 0.5 mg fluoride ion (F-) from 1.1 mg of sodium fluoride (NaF). For use as a dental caries preventative in pediatric patients. Sugar-free and saccharin-free. **Active Ingredient:** Sodium fluoride 0.11% (w/v). **Other Ingredients:** Citric acid, methyl paraben, peach flavor, purified water, red #33, sodium benzoate, sodium fluoride, sucralose, yellow #6.

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 demineralization and by inhibiting the cariogenic microbial process.

USAGE

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. Sodium Fluoride Drops 0.5 mg were developed to provided systemic fluoride for use as a supplement for patients living in areas where the drinking water fluoride level does not exceed 0.6 ppm F. See guidelines for supplementation from ADA and AAP.

CONTRAINDICATIONS

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

WARNINGS

See "CONTRAINDICATIONS" above.

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 ophthalmic use.

ADVERSE REACTIONS

Allergic rash or other idiosyncrasies have been rarely reported. To report **SUSPECTED ADVERSE REACTIONS**, contact H2-Pharma at 1-866-592-6438 or the FDA at 1-800-FDA-1088 or www.fda.gov/med-watch.

OVERDOSAGE

Prolonged daily ingestion of excessive fluoride will result in varying degrees of dental fluorosis. For safety purposes, the total amount of sodium fluoride in a 50 mL bottle of Sodium Fluoride Drops 0.5 mg (25 mg F) conforms with the recommendations of the American Dental Association for the maximum to be dispended at one time.

DOSAGE AND ADMINISTRATION

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

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[1] Conforms to new ADA and AAP guidelines for supplementation.

HOW SUPPLIED

Sodium Fluoride Drops 0.5 mg are available in 50 mL bottles with an accompanying calibrated dropper.

TAMPER EVIDENT

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

*REFERENCES

Accepted Dental Therapeutics, Ed. 40. American Dental Association, Chicago, 1984, p.339-402.
Jakush, J, New Fluoride schedule adopted. ADA New, May 16, 1994, p. 12, 14.

RECOMMENDED STORAGE

Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP Controlled Room Temperature]. After opening, store away from direct light. Close tightly after each use. REFRIGERATION IS NOT REQUIRED.

Distributed by: **H2-Pharma, LLC**
2010 Berry Chase Place, Montgomery, AL 36117
www.h2-pharma.com

PRINCIPAL DISPLAY PANEL - 50 mL Bottle Label

61269-165-50

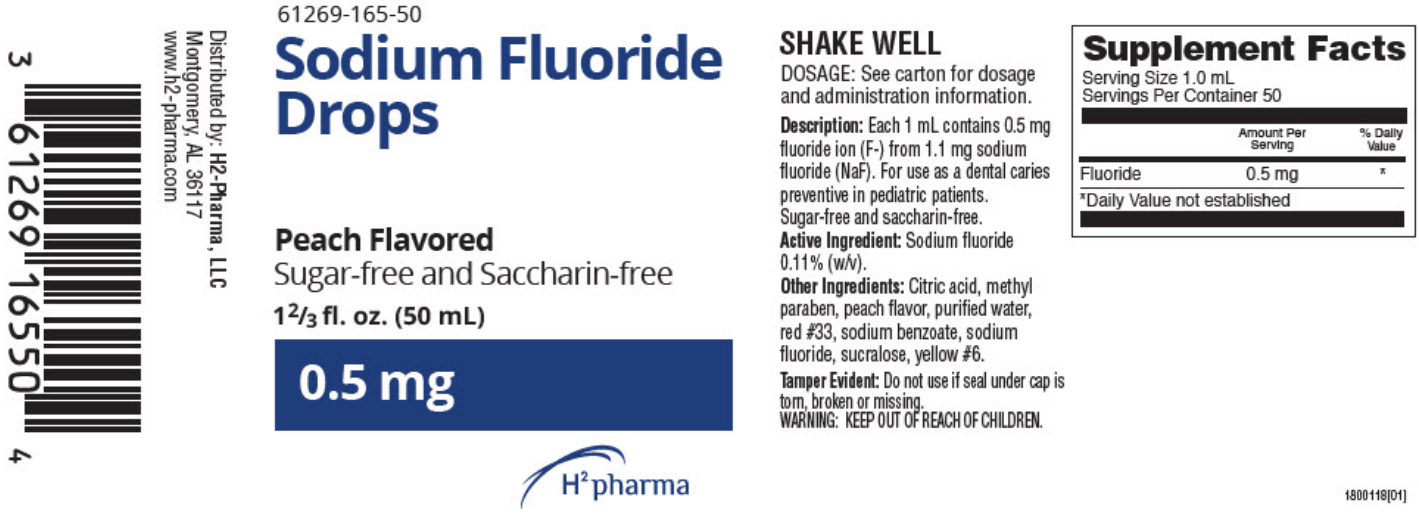
Sodium Fluoride
Drops

Peach Flavored
Sugar-free and Saccharin-free

1 fl. oz. (50 mL)

0.5 mg

H^2 pharma



SODIUM FLUORIDE DROPS

sodium fluoride solution/ drops

Product Information			
Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:61269-165
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEACH (UNII: 3OKE88I3QG)	
WATER (UNII: 059QF0KO0R)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:61269-165-50	1 in 1 CARTON		
1		50 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		01/04/2017	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving	% Daily Value
color	
flavor	

Labeler - H2-Pharma, LLC (028473634)

Revised: 2/2020 H2-Pharma, LLC