

**AVANT- sodium fluoride liquid**  
**Dharma Research, 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](#).*

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**INDICATIONS AND USAGE**

This is a one-minute, ready-to-use fluoride treatment rinse for in-office patient use. Remove cap from bottle and insert enclosed pump into bottle and tighten. Pump ½ oz into a cup. Instruct patient to thoroughly rinse the entire amount around and between teeth for one minute, then spit-out rinse. Repeat the procedure to ensure maximum benefit. Instruct patient not to eat or drink for at least 30 minutes.

**DOSAGE FORM AND STRENGTH**

Liquid containing 2% sodium fluoride

**CONTRAINDICATIONS**

Avoid use in patients with known hypersensitivity to fluoride

**WARNINGS AND PRECAUTIONS**

**Do not swallow. Keep out of reach of children.** Read prescribing information fully before using this product. Use in children less than 6 years of age requires special supervision to prevent swallowing. If product is accidentally swallowed in quantities greater than would normally occur with a rinse, seek medical help right away.

**ADVERSE REACTIONS**

To report suspected adverse reactions, contact Dharma Research, Inc. at 1-877-833-3725 or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)

**DESCRIPTION**

Avant Fluoride Oral Rinse is a flavored, pH neutral 2.0% sodium fluoride treatment rinse that aids in the prevention of dental decay.

ACTIVE INGREDIENT: Sodium Fluoride, 2.0%

INACTIVE INGREDIENTS: Flavor, Water, Sodium Benzoate, Sodium Citrate, Saccharin Sodium, Xylitol

**HOW SUPPLIED/STORAGE**

64 fluid ounces (1.9 L) in a plastic bottle with dispensing pump included. Store at room temperature 59-86°F (15-30°C). Protect from freezing.

**Avant Sodium Fluoride Oral Rinse**

2.0% Neutral Sodium Fluoride

Rx Only

Dye Free

With Xylitol

Gluten Free

64 fl. oz. (1.9 L)

Fruit Punch

Manufactured by:

Dharma Research, Inc., 5220 NW 72nd Avenue, Unit 15, Miami, FL, 33166

1-877-833-3725

www.avant-dental.com

Label Revision A, 11/03/2020

NDC 53045-268-64

**Avant**

**Fluoride Oral Rinse**

2.0% Neutral Sodium Fluoride

dye free with xylitol gluten free

Rx Only

64 fl. oz. (1.9 L) Fruit Punch

**Avant Fluoride Oral Rinse, Sodium Fluoride 2.0% oral rinse**

**INDICATIONS AND USAGE:** This is a one-minute, ready-to-use fluoride treatment rinse for in-office patient use. Remove cap from bottle and insert enclosed pump into bottle and tighten. Pump 1/2 oz into a cup. Instruct patient to thoroughly rinse the entire amount around and between teeth for one minute, then spit-out rinse. Repeat the procedure to ensure maximum benefit. Instruct patient not to eat or drink for at least 30 minutes.

**DOSAGE FORMS AND STRENGTHS:** Liquid containing 2.0% sodium fluoride.

**CONTRAINDICATIONS:** Avoid use in patients with known hypersensitivity to fluoride.

**WARNING AND PRECAUTIONS:** Do not swallow. Keep out of reach of children. Read prescribing information fully before using this product. Use in children less than 6 years of age requires special supervision to prevent swallowing. If product is accidentally swallowed in quantities greater than would normally occur with a rinse, seek medical help right away.

**ADVERSE REACTIONS:** To report suspected adverse reactions, contact Dharma Research, Inc. at 1-877-833-3725 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

**DESCRIPTION:** Avant Fluoride Oral Rinse is a flavored, pH neutral 2.0% sodium fluoride treatment rinse that aids in the prevention of dental decay.

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**HOW SUPPLIED / STORAGE:** 64 fluid ounces (1.9 L) in a plastic bottle with dispensing pump included. Store at room temperature 59-86 F (15°-30° C). Protect from freezing.

Revision A 11/03/2020  
Re-order #: 156\_0133  
MADE IN USA

3 53045 00439 118

Manufactured by:  
**DHARMA**  
RESEARCH, INC.  
5220 N.W. 72 Avenue  
Unit 15, Miami, FL 33166  
1-877-833-3725  
WWW.AVANT-DENTAL.COM

## AVANT

sodium fluoride liquid

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:53045-268
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2 g in 1 L

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	FRUIT PUNCH	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-268-64	1.9 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/22/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/22/2021	

**Labeler** - Dharma Research, Inc. (078444642)

**Registrant** - Dharma Research, Inc. (078444642)

Establishment			
Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-268)

Revised: 1/2021

Dharma Research, Inc.