

**IONITE R- 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**

Ionite R 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.

**Ionite R Sodium Fluoride Rinse**

2.0% Neutral Sodium Fluoride

Dye Free

Spearmint

With Xylitol

Gluten Free

Rx Only

64 fl. oz. (1.9 L)

Manufactured by:

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

1-877-833-3725

NDC 53045-265-64

Label Revision B, 10/29/13



## IONITE R

sodium fluoride liquid

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-265
Route of Administration	DENTAL, ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	38 g in 1 L

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
XYLITOL (UNII: VCQ006KQ1E)	

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	SPEARMINT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-265-64	1.9 L in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/03/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/03/2013	

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

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-265)

Revised: 11/2020

Dharma Research, Inc.