

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](#).

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

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

Fruit Punch
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

www.dharmaresearch.com

NDC 53045-266-64

Label Revision B, 10/29/13

IONITE R

sodium fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:53045-266
Route of Administration	DENTAL, ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYZ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	38 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
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:53045-266-64	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(53045-266)

Revised: 11/2020

Dharma Research, Inc.