IONITE H- sodium fluoride, potassium nitrate gel, dentifrice
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.

Ionite H Neutral Fluoride Gel, Sodium Fluoride, 1.1%, Potassium Nitrate, 5%, oral gel

INDICATIONS AND USAGE

This is a fluoride and potassium nitrate gel intended to aid in the prevention of dental decay and to help treat tooth sensitivity to cold, heat, sweets, acids, or contact.

DOSAGE AND ADMINISTRATION

Use twice per day (morning and evening) in place of regular toothpaste or as recommended by a dentist or physician.

Adults and children 12 years of age and older: Twist off cap and remove foil seal. Apply at least a 1 inch strip gel onto a soft bristle tooth brush. Brush teeth thoroughly for at least 1 minute, spit out, and rinse mouth thoroughly. Make sure to brush all sensitive areas of the teeth.

Children under 12 years of age: consult a dentist or physician.

DOSAGE FORMS AND STRENGTHS

Gel containing 1.1% sodium fluoride and 5% potassium nitrate.

CONTRAINDICATIONS

Avoid use in patients with known hypersensitivity to fluoride. Do not use in pediatric patients under 12 unless directed by a dentist or physician.

WARNINGS AND PRECAUTIONS

Do not swallow.

Keep out of reach of children.

Read prescribing information fully before using this product. If product is accidentially swallowed in quantities greater than would normally occur with a toothpaste, seek medical help right away.

Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens.

Do not use this product for longer than 4 weeks unless recommended by a dentist or physician.

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 H Neutral Fluoride Gel is a flavored, pH neutral 1.1% sodium fluoride, 5% potassium nitrate gel

that aids in the prevention of dental decay and hleps to treat sensitive teeth.

ACTIVE INGREDIENTS

Sodium Fluoride, 1.1%; Potassium Nitrate, 5%

INACTIVE INGREDIENTS

Alpha-tocopheryl, carbopol, edetic acid, flavor, glycerin, sodium hydroxide, sodium polymetaphosphate, tricalcium phosphate, water, xylitol

HOW SUPPLIED/STORAGE

4.3 ounces (122 g) in a plastic tube. Store at room temperature 59 – 86°F (15 – 30°C).

Manufactured by Dharma Research, Inc.

www.dharmaresearch.com

5220 N.W. 72 Avenue, Unit 15

Miami, FL 33166

1-877-833-3725

Ionite H

NDC 53045-281-04

Home Care

1.1% Neutral Fluoride Gel

with Xylitol and Vitamin E

Bubble Gum

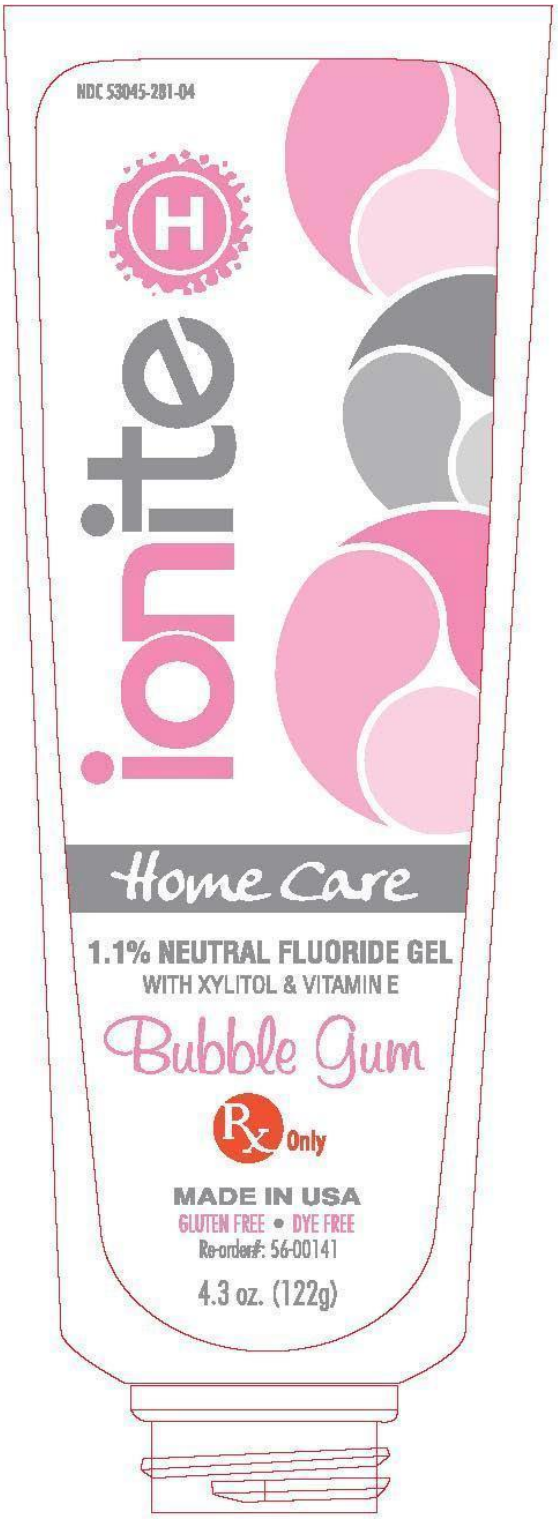
Rx Only

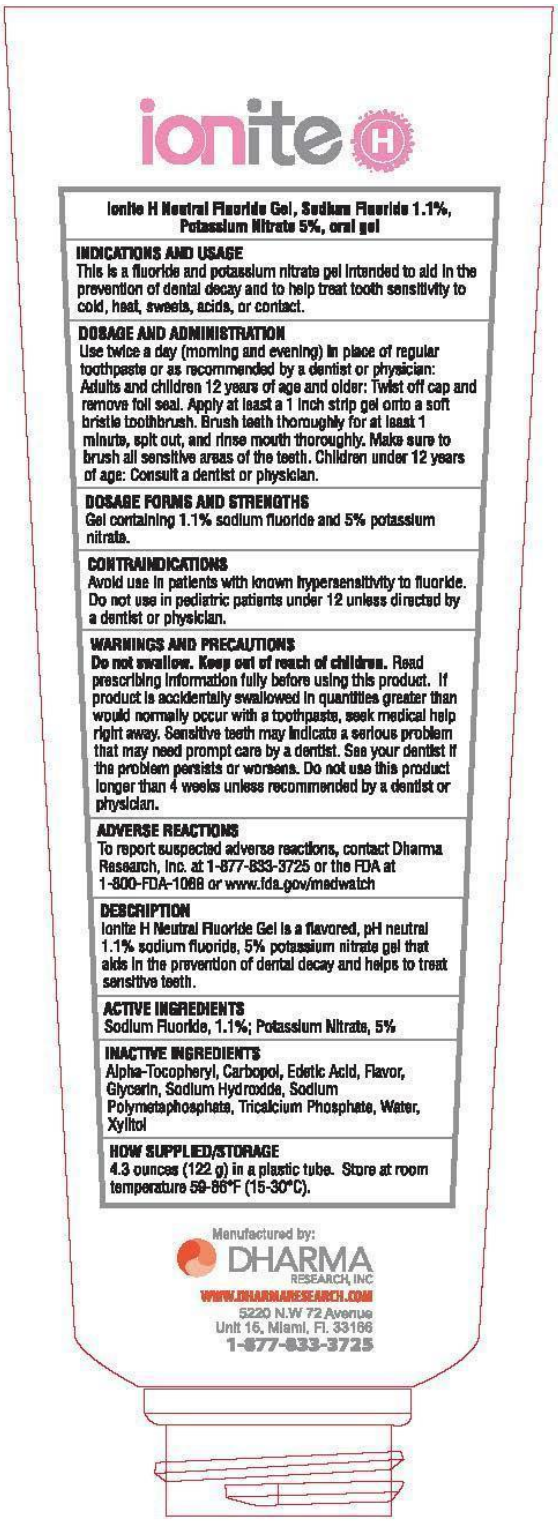
Made in USA

Gluten Free Dye Free

Re-order#: 56-00141

4.3 oz. (122 g)





IONITE H

sodium fluoride, potassium nitrate gel, dentifrice

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:53045-281
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 100 g
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	5 mg in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETIC ACID (UNII: 9G34HU7RV0)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
TRICALCIUM PHOSPHATE (UNII: K4C08XP666)	
water (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:53045-281-04	122 g in 1 TUBE; Type 0: Not a Combination Product	08/02/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/02/2015	

Labeler - Dharma Research, Inc. (078444642)

Establishment

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-281)

Revised: 8/2015 Dharma Research, Inc.