

IONITE H- stannous fluoride gel, dentifrice
Dharma Research, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Stannous fluoride, 0.4%

Purpose

Anticavity

Uses

Aids in the prevention of dental cavities (caries).

Warnings

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Do not swallow.

Supervision of children is required when using this product. Developing teeth of children under six years of age may become permanently discolored if excessive amounts are repeatedly swallowed.

Directions

- This is not a toothpaste. Read directions carefully before using.
- Adults and children 6 years of age and older:
 - o Use once per day after brushing teeth thoroughly with toothpaste
 - o Twist off cap to remove foil seal
 - o Apply a small amount to a toothbrush and brush thoroughly on all tooth surfaces.
 - o Allow the gel to remain on your teeth for 1 minute
 - o Spit out. Do not swallow
 - o Do not eat, drink, or rinse for at least 30 minutes
- Children under 6: consult a dentist or doctor

Other Information

- Store at room temperature 59 – 86°F (15 – 30°C)
- This product may produce surface staining of the teeth. Adequate tooth brushing may prevent these stains which are not harmful or permanent and may be removed by your dentist

Inactive Ingredients

Carbopol, citric acid, flavor, glycerin, sodium hydroxide, water, xylitol

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 53045-270-04

Home Care

0.4% Stannous Fluoride Gel with Xylitol

Anticavity Fluoride Preventative Treatment Gel

Spearmint

Made in USA

Gluten Free Dye Free

Reorder#: 56-00130

4.3 oz. (122 g)

NDC 53045-270-04



ionite

Home Care

0.4% STANNOUS
FLUORIDE GEL
WITH XYLITOL

ANTICAVITY FLUORIDE
PREVENTIVE TREATMENT GEL

Spearmint

MADE IN USA
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Drug Facts

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Manufactured by:
 **DHARMA**
RESEARCH, INC.
WWW.DHARMARESEARCH.COM
5220 N.W. 72 Avenue
Unit 15, Miami, FL 33168
1-877-833-3725

IONITE H

stannous fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53045-270
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.4 mg in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	SPEARMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-270-04	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
OTC monograph final	part355	08/02/2015	

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

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-270)

Revised: 8/2015

Dharma Research, Inc.