

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

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**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 doctors

**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](http://www.dharmaresearch.com)

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1-877-833-3725

**Ionite H**

NDC 53045-271-04

Home Care

0.4% Stannous Fluoride Gel with Xylitol  
 Anticavity Fluoride Preventative Treatment Gel  
 Bubble Gum  
 Made in USA  
 Gluten Free Dye Free  
 Reorder#: 56-00131  
 4.3 oz. (122 g)

**IONITE H**

stannous fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53045-271
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 HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C00X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0K00R)	
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:53045-271-04	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 Drug	M021	08/02/2015	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Dharma Research, Inc.		078444642	manufacture(53045-271)

Revised: 10/2023

Dharma Research, Inc.