

**IONITE H- stannous fluoride mouthwash**  
**Dharma Research, Inc.**

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**Active Ingredient**

Stannous Fluoride, 0.63%

**Purpose**

Anticavity/Antigingivitis

**Uses**

- Aids in the prevention of dental decay
- Helps prevent gingivitis
- Helps interfere with harmful effects of plaque associated with gingivitis

**Warnings**

**Keep out of reach of children** under 6 years of age. If more than used for rinsing is swallowed, get medical help or contact a Poison Control center right away.

**Do not** swallow.

**Directions**

- Do not use before mixing with water
- Adults and children 6 years of age and older:
  - Use once per day after brushing your teeth with toothpaste
  - Remove cap and replace with pump
  - Rotate spout counter clockwise to extend
  - Depress pump until rinse comes to the tip of the pump
  - Pump 1/8 fl. oz. into a cup.
  - Add water to the line (1 fl. oz.) on cup.
  - Mix using bristle end of toothbrush
  - Vigorously swish rinse between your teeth for 1 min. and then spit out.
  - Do not swallow the rinse
  - Do not eat or drink for 30 min. after rinsing
  - Instruct children under 12 in good rinsing habits to minimize swallowing.
  - Supervise children as necessary until capable of using without supervision
- 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**

Edetic acid, Flavor, Glycerin, Saccharin Sodium, Xylitol

Manufactured by Dharma Research, Inc.

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

5220 N.W. 72 Avenue, Unit 15

Miami, FL 33166

1-877-833-3725

Reorder#: 56-00136

**Ionite H**

NDC 53045-276-10

PERIO MAINTENANCE ANTICAVITY/ANTINGINGIVITIS RINSE

0.63 Stannous Fluoride Concentrate with Xylitol

Alcohol Free

Fruit Punch

**IMPORTANT: Read directions for proper use.**

Made in USA

Dye Free Gluten Free Paraben Free

Home Care

10 fl. oz. (296 mL)

**IONITE H**  
stannous fluoride mouthwash

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53045-276
<b>Route of Administration</b>	DENTAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>STANNOUS FLUORIDE</b> (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.63 mg in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>EDETIC ACID</b> (UNII: 9G34HU7RV0)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

**Product Characteristics**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53045-276-10	269 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	08/03/2015	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	08/03/2015	

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

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Dharma Resarch, Inc.		078444642	manufacture(53045-276)

Revised: 10/2023

Dharma Research, Inc.