

**FRESHMINT ANTICAVITY FLUORIDE- sodium fluoride gel, dentifrice**  
**New World Imports, Inc**

**Drug Facts**

Sodium Fluoride - 0.22% (0.1% w/v fluoride ion)

Anticavity

**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.

aids in the prevention of dental cavities

**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.

**Adults and children 2 years of age and older:** Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician.

- do not swallow
- instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing use a pea-sized amount)
- supervise children as necessary until capable of using without supervision

**Children under 2 years:** Ask a dentist or doctor

Treated Water, Sorbitol, Carbomer, Sodium Lauryl Sulfate, Flavor, PEG-32, Sodium Saccharin, Silica, Cellulose Gum, Sodium Hydroxide, Disodium EDTA



NET WT. 2.75 OZ (78g)

Drug Facts		Drug Facts (continued)
<b>Active Ingredient</b> Sodium fluoride - 0.22% (0.1% w/v fluoride ion).....	<b>Purpose</b> Anticavity	twice a day, or as instructed by a dentist or doctor <ul style="list-style-type: none"> <li>■ do not swallow</li> <li>■ instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing use a pea-sized amount)</li> <li>■ supervise children as necessary until capable of using without supervision</li> <li>■ <b>Children under 2 years of age:</b> consult a dentist or doctor</li> </ul>
<b>Uses</b> aids in the prevention of dental cavities		<b>Inactive Ingredients</b> Treated Water, Sorbitol, Carbomer, Sodium Lauryl Sulfate, Flavor, PEG-32, Sodium Saccharin, Silica, Cellulose Gum, Sodium Hydroxide, Disodium EDTA
<b>Warnings</b> <b>Keep out of reach of children.</b> If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.		
<b>Directions</b> ■ <b>Adults and children 2 years of age and older:</b> brush teeth thoroughly, preferably after each meal or at least		

Exp. Date & Batch No. on crimp.



3x8mm

1mm

XXXXMMDDYY

# FRESHMINT ANTICAVITY FLUORIDE

sodium fluoride gel, dentifrice

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51824-068
<b>Route of Administration</b>	DENTAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Sodium Fluoride</b> (UNII: 8ZYQ1474W7) (Fluoride Ion - UNII:Q80VPU408O)	Fluoride Ion	2.2 mg in 1 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>Sodium Lauryl Sulfate</b> (UNII: 368GB5141J)	
<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)	
<b>Saccharin Sodium</b> (UNII: SB8ZUX40TY)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Carboxymethylcellulose Sodium</b> (UNII: K679OBS311)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	

## Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-068-01	7.9 g in 1 PACKET; Type 0: Not a Combination Product	09/17/2010	
2	NDC:51824-068-02	17 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
3	NDC:51824-068-03	24 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
4	NDC:51824-068-04	43 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
5	NDC:51824-068-05	78 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
6	NDC:51824-068-06	130 g in 1 TUBE; Type 0: Not a Combination Product	09/17/2010	
	NDC:51824-068-07	191 g in 1 TUBE; Type 0: Not a Combination Product		

7	NDC:51824-068-07	181 g in 1 TUBE; Type O: Not a Combination Product	09/17/2010	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M021		09/17/2010	

**Labeler** - New World Imports, Inc (075372276)

Revised: 1/2025

New World Imports, Inc