

**FRESHDENT CAVITY PROTECTION ANTICAVITY- sodium monofluorophosphate paste, dentifrice**

**FreshDent LLC**

*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.*

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**FreshDent Anticavity Toothpaste**

**Active Ingredients**

Sodium Monofluorophosphate 0.76% (0.085% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

Aids in the prevention of dental cavities

**Warnings**

**Keep out of Reach of children**

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

**Directions**

- 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 doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

**Inactive Ingredients**

Sorbitol, Water, Hydrated Silica, Calcium Carbonate, Sodium Lauryl Sulfate, Carboxymethyl Cellulose, Flavor, Titanium Dioxide, Sodium Saccharin, Sodium Methyl Paraben, FD&C Blue 1.

**Questions?**

+1-512-653-8814

**Package Label**

Anticavity Toothpaste

FreshDent

we care

Cavity Protection

Strengthens teeth with Active Fluoride

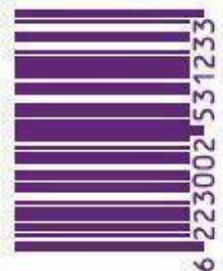
Net Wt. 0.85 oz (24 g)

Distributed by: FreshDent LLC Crockett, TX 75835 www.freshdent.net Made in Egypt

- ✔ FreshDent CAVITY PROTECTION toothpaste has been specially formulated with Sodium Monofluorophosphate to fight cavities and plaque, and to reduce tooth decay.
- ✔ Despite all attention brought to this product, if you are entirely satisfied, please let us know your comments and suggestions.
- ✔ Expiration Date: 3 years from production date. See end of tube for production date. Store in a cool dry place out of direct light.



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<p><b>Drug Facts</b></p>	<p><b>Drug Facts (continued)</b></p>
<p><b>Active ingredient</b></p> <p>Sodium Monofluorophosphate 0.76% (0.085% w/v fluoride ion) ..... Purpose Anticavity</p>	<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• 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 doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.</li> <li>• Children under 2 years of age: Consult a dentist or doctor.</li> </ul>
<p><b>Use</b></p> <p>Aids in the prevention of dental cavities</p>	<p><b>Inactive ingredients</b></p> <p>Sorbitol, Water, Hydrated Silica, Calcium Carbonate, Sodium Lauryl Sulfate, Carboxymethyl Cellulose, Flavor, Titanium Dioxide, Sodium Saccharin, Sodium Methyl Paraben, FD&amp;C Blue 1.</p>
<p><b>Warnings</b></p> <p>Keep out of reach of children under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.</p>	<p><b>Questions?</b> +1 512-653-8814</p>

# Anticavity Toothpaste



Net Wt. 0.85 oz (24 g)

Strengthens teeth with Active Fluoride

FOR BEST RESULTS, SQUEEZE TUBE FROM THE BOTTOM AND FLATTEN AS YOU GO UP.

**Active ingredient**

Sodium Monofluorophosphate 0.76% (0.085% w/v fluoride ion) ..... Purpose Anticavity

**Use** - Aids in the prevention of dental cavities

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

**Directions**- 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 doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.

**This Unit Not Labeled For Retail Sale.**  
**This unit is packaged in an outer container.**  
**Please see outer container for complete drug facts informations.**

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## FRESHDENT CAVITY PROTECTION ANTICAVITY

sodium monofluorophosphate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69338-002
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.85 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>METHYL PARABEN SODIUM</b> (UNII: CR6K9C2NHK)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69338-002-01	1 in 1 CARTON		
1		24 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/06/2014	

**Labeler** - FreshDent LLC (079303265)

### Establishment

Name	Address	ID/FEI	Business Operations
Swiss Egyptian Co. For Oral Care Products and Cosmetics		366442234	manufacture(69338-002)

Revised: 11/2014

FreshDent LLC