

**FRESHDENT KIDS STRAWBERRY ANTICAVITY TOOTH- sodium fluoride 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.

FreshDent Kids Strawberry Anticavity Toothpaste

Active Ingredients

Sodium Fluoride 0.188% (0.065% w/v fluoride ion)

Purpose

Anticavity

Use

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, Glycerin, Water, Silica, Carboxymethyl Cellulose, Lauryl Sulfate, Sodium Saccharin, Diazolidinyl Urea, Strawberry Flavor, Menthol, D & C Red No. 33.

Questions?

+1-512-653-8814

Package Label

Strawberry Anticavity toothpaste

FreshDent Kids

we care

Net Wt. 0.85 oz (24 g)

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

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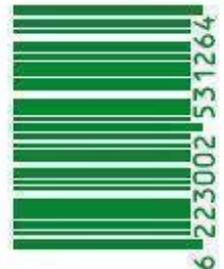
FreshDent KIDS Gel has been shown to be an effective decay preventive dentifrice that can be of significant value when used as directed in a conscientiously applied program of oral hygiene and regular professional care

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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Drug Facts

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Use

Aids in the prevention of dental cavities

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Drug Facts (continued)

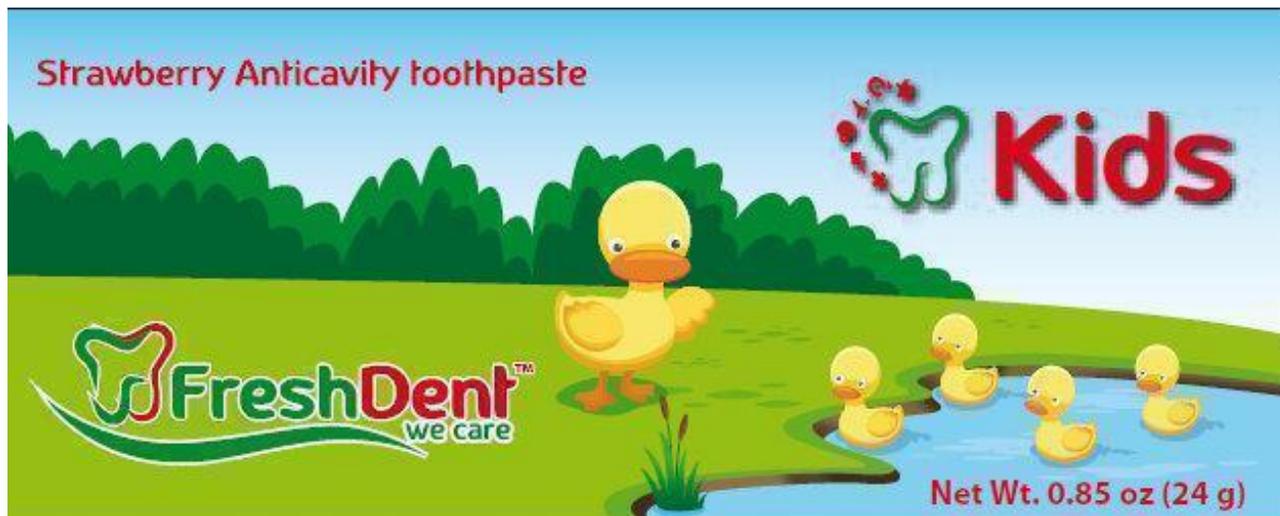
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FOR BEST RESULTS, SQUEEZE TUBE FROM THE BOTTOM AND FLATTEN AS YOU GO UP.

Active ingredient

Sodium Fluoride 0.188% (0.065% 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.

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**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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Made in Egypt

FRESHDENT KIDS STRAWBERRY ANTICAVITY TOOTH

sodium fluoride paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69338-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.65 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CARBOXYMETHYLCELLULOSE (UNII: 05JZI7B19X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
MENTHOL (UNII: L7T10EIP3A)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	STRAWBERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69338-001-01	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(69338-001)

Revised: 11/2014

FreshDent LLC