

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
Family Dollar Stores, Inc

Family Wellness 163.005/163AG
Anticavity Fluoride Rinse

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warning

for this product

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older:

- use twice daily after brushing your teeth with toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision
- children under 12 years of age: consult a dentist or doctor

Other information

- store at controlled room temperature 20°-25° C (68° - 77°F)
- cold weather may temporarily cloud this product

Inactive ingredients

water, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

Disclaimer

*This product is not manufactured or distributed by Johnson & Johnson Corporation, distributor of Listerine[®] Total Care Fresh Mint Anticavity Mouthwash.

Adverse Reaction

DISTRIBUTED BY: MIDWOOD BRANDS, LLC

500 VOLVO PKWY, CHESAPEAKE, VA 23320 USA

MADE IN THE US WITH US AND FOREIGN COMPONENTS.

NOT 100% SATISFIED? Return within 30 days to the store of purchase for a refund (with receipt) or Exchange.

DSP-TN-21091

DSP-MO-20087

principal display panel

Sealed with printed neckband for your protection.

Do not use if band around cap is broken or missing.

FAMILY WELLNESS[™]

COMPARE TO LISTERINE[®] TOTAL CARE FRESH MINT ANTICAVITY MOUTHWASH*

MINT

ANTICAVITY FLUORIDE RINSE

Sodium Fluoride and Acidulated Phosphate Topical Solution

MINT FLAVOR ANTICAVITY FLUORIDE MOUTHWASH

- Multiple benefits in one
- Helps prevent cavities and restore enamel
- Helps strengthen teeth

1 L (1.05 QT) 33.8 FL OZ

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L0021302FA

Drug Facts

Active ingredient Sodium fluoride 0.02% w/v (0.01% w/v fluoride ion)	Purpose Anticavity
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Use aids in the prevention of dental cavities

Warning

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

Directions

- Adults and children 6 years of age and older:
- use twice daily after brushing your teeth with a toothpaste
 - vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
 - do not swallow the rinse
 - do not eat or drink for 30 minutes after rinsing
 - instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
 - supervise children as necessary until capable of using without supervision
 - children under 6 years of age: consult a dentist or doctor

Other information

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SKU 999762



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DSP-MO-20087 L0021302BA

ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55319-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
EUCALYPTOL (UNII: RV6J6604TK)	

METHYL SALICYLATE (UNII: LAV5U5022Y)	
MENTHOL (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
THYMOL (UNII: 3J50XA376E)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319-163-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/14/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	12/14/2011	

Labeler - Family Dollar Stores, Inc (024472631)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment			
Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(55319-163)