

ANTICAVITY- sodium fluoride mouthwash
Liberty Procurement, Inc

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.

Core Values_163.005/163AF/AG Anticavity Mouthwash

Active ingredient

Sodium fluoride 0.0221% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities

Warnings

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 then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- supervise children as necessary until capable of using without supervision
- children under 6 years of age: consult a dentist or doctor

Other information

- store at controlled room temperature 20°-25° C to (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 Healthcare Products, distributor of Listerine Total Care Anticavity Mouthwash

Distributed by
Liberty Procurement Co. Inc.
Union, NJ 07083 USA
www.facevalues.com

SATISFACTION GUARANTEED Or Your Money Back

principal display panel

COREVALUES

Compare to Listerine Total Care Fresh Mint*

Anticavity MOUTHWASH

SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPICAL SOLUTION

MULTIPLE BENEFITS

IN ONE RINSE:

- Helps prevent cavities
- Restores enamel
- Strengthens teeth
- Kills germs that cause bad breath
- Freshens breath
- Leaves mouth feeling clean

IMPORTANT:

Read directions for proper use.

Mint Flavor

1 LITER (1 QT 1.8 fl oz)

Sealed With Printed Neckband For Your Protection

CORE VALUES™

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L0010916FF

Drug Facts

Active ingredient
Sodium fluoride 0.0221% (0.01% w/v fluoride ion)Anticavity

Purpose

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

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

Inactive ingredients water, alcohol (21.6%), sorbitol, poloxamer 407, sodium lauryl sulfate, eucalyptol, flavor, methyl salicylate, thymol, phosphoric acid, sucralose, menthol, disodium phosphate, red 40, blue 1

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DSP-TN-15000
DSP-MO-34
SDS-TN-15012

L0010916BF

ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-163
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:63940-163-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/06/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/06/2016	

Labeler - Liberty Procurement, Inc (804085293)

Registrant - Vi Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(63940-163)

Revised: 9/2023

Liberty Procurement, Inc