

ANTICAVITY- sodium fluoride mouthwash
Rite Aid

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.

Restoring Anticavity Fluoride Mouthwash
581.000/581AA-AB

Active ingredient

Sodium Fluoride 0.02% (0.009% w/v fluoride ion)

Purpose

Anticavity

Use

Aids in the prevention of dental cavities

Warnings

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 6 years of age and older:

- use twice a day 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

Inactive ingredients

water, alcohol (11%), sorbitol, poloxamer 407, propylene glycol, sodium benzoate, flavor, sodium phosphate, polysorbate 20, sodium saccharin, cetylpyridinium chloride, disodium phosphate, calcium disodium EDTA, blue 1

Disclaimer

This product is not manufactured or distributed by Chattem, Inc., distributor of Act Restoring Anticavity Fluoride Mouthwash Cool Mint.*

Claims

Gluten Free

Sugar Free

Paraben Free

Adverse Reaction

DISTRIBUTED BY:

RITE AID, 30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

SATISFACTION GUARANTEE

If you're not satisfied, we'll happily refund your money.

principal display panel

Sealed with printed neckband for your protection

IMPORTANT: read directions for proper use.

Compare to Act Restoring Anticavity Fluoride Mouthwash*

GLUTEN FREE

SUGAR FREE

RESTORING

ANTICAVITY FLUORIDE

MOUTHWASH

REFRESHING MINT

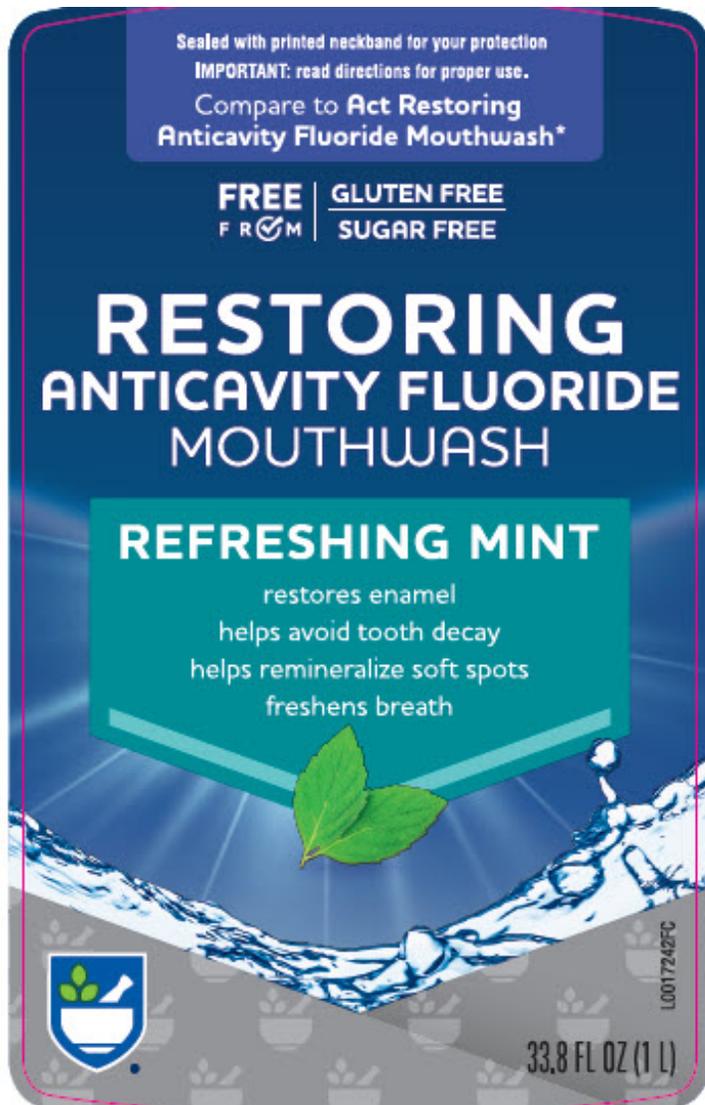
restores enamel

helps avoid tooth decay

helps remineralize soft spots

freshens breath

33.8 FL OZ (1 L)



ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-6877
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-6877-8	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/04/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	12/04/2017	

Labeler - Rite Aid (014578892)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11822-6877)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11822-6877)