

ANTICAVITY- sodium fluoride mouthwash
Wal-Mart Stores, 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.

Restoring Anticavity Fluoride Mouthwash
581.000/581AA-AC

TEP

Sealed With Printed Neckband For Your Protection

Active ingredient

Sodium fluoride 0.02% (0.009% 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 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

Questions

Call 1-888-287-1915

Adverse reaction

Satisfaction guaranteed - Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call 1-888-287-1915.

DISTRIBUTED BY: Wal-Mart Stores, Inc., Bentonville, AR 72716

*This product is not manufactured or distributed by chattem Inc., owner of the registered mark Act Restoring Anticavity Fluoride Mouthwash Cool Mint.

Principal panel display

equate

Compare to Act® Restoring™ Anticavity Fluoride Mouthwash Active Ingredient*

Restoring Anticavity

Fluoride

Mouthwash

- Restores enamel
- Helps remineralize soft spots

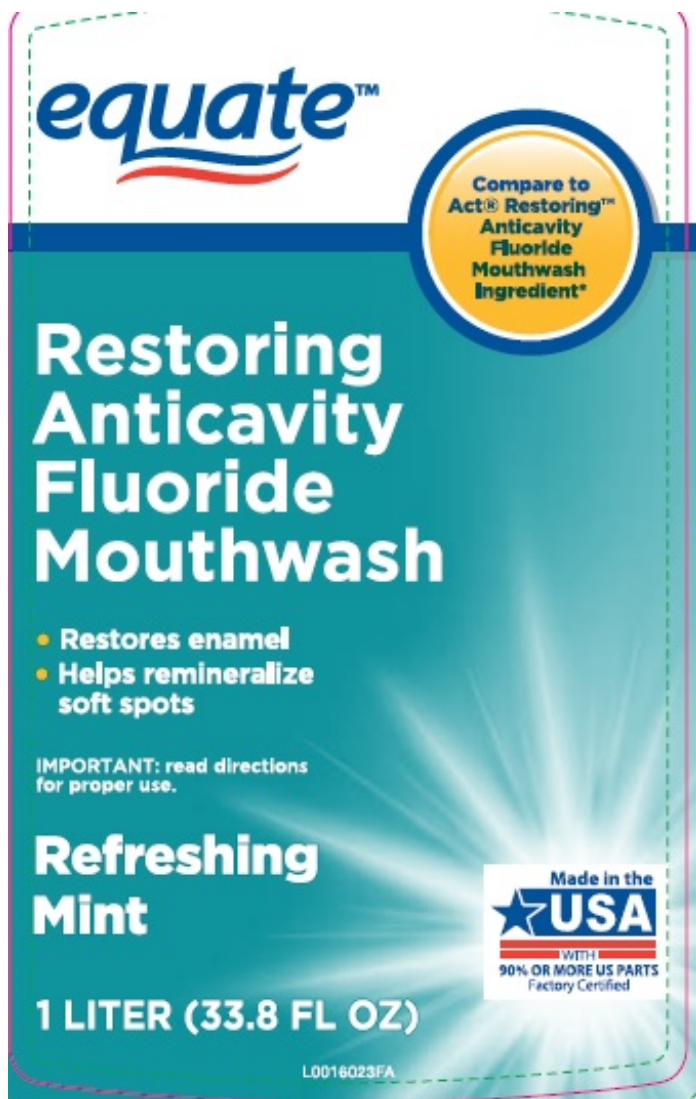
IMPORTANT: read directions for proper use.

Refreshing Mint

Made in the USA WITH 90% OR MORE US PARTS

Factory Certified

1 LITER (33.8 FL OZ)



ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-581
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.2 mg in 1 mL

Inactive Ingredients

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

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
CETYLPIRIDINIUM 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:49035-581-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	09/25/2016	

Labeler - Wal-Mart Stores, Inc (051957769)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(49035-581)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(49035-581)

Revised: 7/2023

Wal-Mart Stores, Inc