

SODIUM FLUORIDE- sodium fluoride mouthwash
Demoulas Super Markets, 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
581.000/581AB

Claims

Leaves your entire mouth feeling clean while it helps strengthen teeth and prevent tooth decay.

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

Adverse reaction

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

Like it or let us make it right.

DSP-TN-21091

DSP-MO-20087

DISTRIBUTED BY

DEMOULAS SUPER MARKETS, INC.

875 EAST STREET

TEWKSBURY, MA 01876

Principal Panel Display

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MARKET BASKET

"MORE FOR YOUR DOLLAR"

compare to Act Restoring Anticavity Fluoride Mouthwash*

Restoring Anticavity Fluoride Mouthwash

ANTICAVITY MOUTHWASH

Restores enamel

Helps avoid tooth decay

Helps remineralize soft spots

Freshens breath

IMPORTANT: read directions for proper use.

33.8 FL OZ (1 L)

Sealed With Printed Neckband
For Your Protection



Compare to Act® Restoring
Anticavity Fluoride Mouthwash*

Restoring Anticavity Fluoride Mouthwash

ANTICAVITY MOUTHWASH

Refreshing Mint

- Restores enamel
- Helps avoid tooth decay
- Helps remineralize soft spots
- Freshens breath

IMPORTANT: read directions for proper use.

33.8 FL OZ (1 L)

L0020367FA

SODIUM FLUORIDE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-581
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:53942-581-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/05/2023	

Labeler - Demoulas Super Markets, Inc (007869647)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(53942-581)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(53942-581)