

ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash
Wakefern Food Corp

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.

Anticavity Fluoride Mouth Rinse 163

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 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
- 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%), sorbitol, poloxamer 407, sodium lauryl sulfate, eucalyptol, flavor, methyl salicylate, thymol, phosphoric acid, sucralose, menthol, disodium phosphate, red 40, blue 1

Adverse reaction

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine Total Care Anticavity Mouthwash.

DISTRIBUTED BY WAKEFERN FOOD CORP.

5000 RIVERSIDE DRIVE
KEASBEY, NJ 08832
1-800-SHOPRITE
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principal display panel

Compare to the Active Ingredient of LISTERINE Total Care Anticavity Mouthwash*

Shop Rite

Anticavity Fluoride MOUTH RINSE

Sodium Fluoride and Acidulated Phosphate Topical Solution

Helps strengthen teeth

- Helps prevent cavities
- Helps restore enamel
- Helps kill germs that cause bad breath

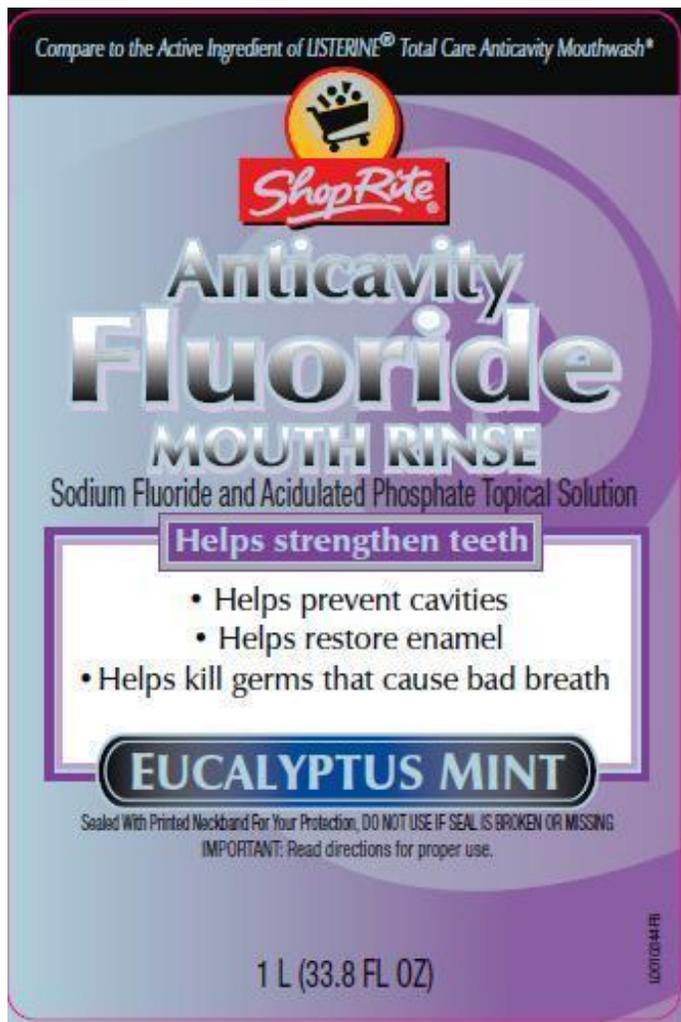
EUCALYPTUS MINT

Sealed With Printed Neckband For Your Protection, DO NOT USE IF SEAL IS BROKEN OR MISSING

IMPORTANT: Read directions for proper use

1 L (33.8 FL OZ)

163.004/163AE



ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-163
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: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EUCALYPTOL (UNII: RV6J6604TK)	

METHYL SALICYLATE (UNII: LAV5U5022Y)
THYMOL (UNII: 3J50XA376E)
PHOSPHORIC ACID (UNII: E4GA8884NN)
sucralose (UNII: 96K6UQ3ZD4)
MENTHOL (UNII: L7T10EIP3A)
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-163-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/05/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/05/2010	

Labeler - Wakefern Food Corp (069722418)

Registrant - Vi Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(41190-163)