

ANTICAVITY- sodium fluoride rinse

Kroger Co

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.

Drug Facts

Active ingredient

Active ingredient

Sodium fluoride 0.055% (0.02% w/v fluoride ion)

Purpose

Purpose

Anticavity rinse

Use

Use aids in the prevention of dental cavities

Warnings

Warnings

Keep out of reach of children

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately

Directions

Directions

- adults and children 6 years of age and older: use once a day after brushing your teeth with toothpaste
- remove cap
- pour 10 milliliters (10 mL mark on inside of cap); do not fill above the 10 mL mark
- vigorously swish 10 milliliters 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

Other information

- store at room temperature

Inactive ingredients

Inactive ingredients benzyl alcohol, calcium disodium EDTA, cetylpridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

Adverse Reactions

Comments or Questions?

800-632-6900 or www.kroger.com

DISTRIBUTED BY

THE KROGER CO.

CINCINNATI, OH 45202

Principal Display Panel

Sealed with printed neckband for your protection.

IMPORTANT: read directions for proper use

Kroger

Quality Guaranteed

KIDS

Anticavity

Fluoride Rinse

strong cavity protection

alcohol free

helps strengthen teeth

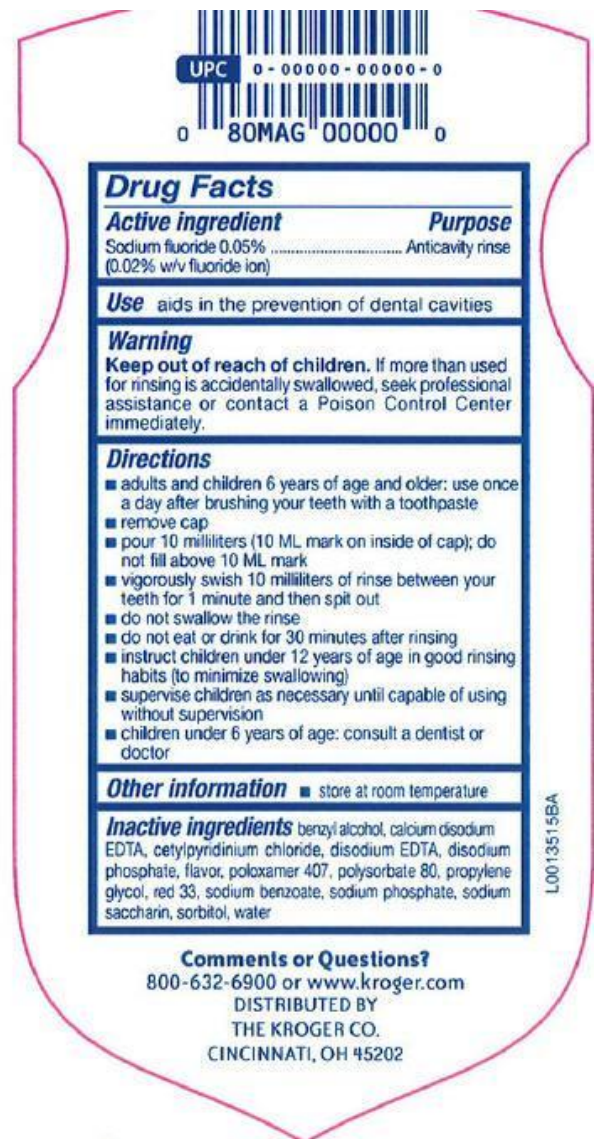
helps prevent cavities

16.0 FL OZ

(500 mL)

bubblegum

Flavor



ANTICAVITY

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	10.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	

EDETATE DISODIUM (UNII: 7FLD91C86K)
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)
POLO XAMER 407 (UNII: TUF2IVW3M2)
POLYSORBATE 80 (UNII: 6OZP39ZG8H)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
SODIUM BENZOATE (UNII: OJ245FE5EU)
SODIUM PHOSPHATE (UNII: SE337SVY37)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
SORBITOL (UNII: 506T60A25R)
WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-004-77	500 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/18/2013	

Labeler - Kroger Co (006999528)

Registrant - Vi-Jon (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(30142-004)