

KIDS FLOURIDE RINSE- sodium fluoride rinse
Army + Air Force Exchange Service

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 Rinse 004

Active ingredient

Sodium Fluoride 0.05% (0.02% w/v fluoride ion)

Purpose

Anticavity rinse

Use

aids in the prevention of dental cavities

Warnings

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

- adults and children 6 years of age and older: use once a day after brushing your teeth with a 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

- store at room temperature

Inactive ingredients

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

Adverse reactions

*This is not manufactured or distributed by Chattem, Inc., distributor of Act

SATISFACTION GUARANTEED OR YOUR MONEY BACK

Manufactured for Your Military Exchanges

By: Vi-Jon

8515 Page Ave

St. Louis, MO 83114

004.002/004AE

principal display panel

Compare to the active ingredient of Act Bubblegum Blowout Anticavity Kids Fluoride Rinse
exchange select

KIDS

ANTICAVITY FLUORIDE RINSE

ALCOHOL FREE

- Strong cavity protection
- Helps strengthen teeth
- Freshens Breath

BUBBLE GUM FLAVOR

IMPORTANT: read directions for proper use.

quality value

18 FL OZ (532 mL)



KIDS FLOURIDE RINSE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55301-004
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)
POLOXAMER 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:55301-004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/09/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/09/2011	

Labeler - Army + Air Force Exchange Service (001695568)

Registrant - Vi-Jon (150931459)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		150931459	manufacture(55301-004)