KIDS FLOURIDE RINSE- sodium fluoride rinse Military Exchanges

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, Bubble Gum 004.002/004AE

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 milliters (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 Anticavity Fluoride Rinse.

"SATISFACTION GUARANTEED OR YOUR MONEY BACK."

Manufactured for Your Military Exchanges

By: Vi-Jon 8515 Page Ave

St. Louis, MO 83114

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)

quality value





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:Q80VPU4080) 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: 60ZP39ZG8H)	
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)	

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

Labeler - Military Exchanges (001695568)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(55301-004)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(55301-004)

Revised: 1/2023 Military Exchanges