

ACT ANTICAVITY FLUORIDE KIDS GROOVY GRAPE- sodium fluoride rinse
Chattem, Inc.

ACT Anticavity Fluoride Rinse Kids Groovy Grape

ACT

Anticavity Kids Rinse Groovy Grape 0.05%

Drug Facts

Active ingredient

Sodium fluoride 0.05% (0.02% 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 6 years of age and older:

- use once a day after brushing your teeth with a toothpaste
- remove cap
- hold bottle upright and squeeze. Fill to FILL LINE.
- pour out. Only the correct 10 milliliters dose will pour out.
- 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

■ do not use if safety seal is broken or missing

Inactive ingredients

benzyl alcohol, blue 1, calcium disodium EDTA, cetylpyridinium chloride, disodium phosphate, flavor, poloxamer 407, polysorbate 20, potassium sorbate, propylene glycol, red 33, sodium benzoate, sodium phosphate, sorbitol, sucralose, water

PRINCIPAL DISPLAY PANEL

ACT

Kids

ANTICAVITY

FLUORIDE RINSE

GROOVY GRAPE

16.9 fl oz (500 mL)



ACT ANTICAVITY FLUORIDE KIDS GROOVY GRAPE

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0945
Route of Administration	TOPICAL		

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	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)				
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)				
POLOXAMER 407 (UNII: TUF2IVW3M2)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
D&C RED NO. 33 (UNII: 9DBA0SBB0L)				
SODIUM BENZOATE (UNII: OJ245FE5EU)				
SODIUM PHOSPHATE (UNII: SE337SVY37)				
SORBITOL (UNII: 506T60A25R)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color		Score		
Shape		Size		
Flavor	GRAPE	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0945-0	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M021	04/01/2019	

Labeler - Chattem, Inc. (003336013)