ACT ANTICAVITY FLUORIDE RINSE KIDS SCOOBY DOO- sodium fluoride rinse Chattem, Inc.

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.

ACT Anticavity Fluoride Rinse Kids Scooby Doo

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 accidently swallowed, get medical help or contact 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

- contains FD&C yellow no.5 (tartrazine) as a color additive
- do not use if safety seal is broken or missing

Inactive ingredients

calcium disodium EDTA, cetylpyridinium chloride, disodium phosphate, flavor, green 3, poloxamer 407, polysorbate 20, potassium sorbate, propylene glycol, sodium benzoate, sodium phosphate, sorbitol, sucralose, water, yellow 5 (309-023)

Principal Display Panel

ACT Kids Anticavity Fluoride Rinse Scooby-Doo! Kiwi Watermelon Sodium Fluoride 0.05% 16.9 fl oz (500 mL)





ACT ANTICAVITY FLUORIDE RINSE KIDS SCOOBY DOO

sodium fluoride rinse

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:41167-0934
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (FLUORIDE ION)	FLUORIDE ION	0.5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
EDETATE CALCIUM DISODIUM ANHYDROUS	
CETYLPYRIDINIUM CHLO RIDE	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US	
FD&C GREEN NO. 3	
POLOXAMER 407	
POLYSORBATE 20	
POTASSIUM SORBATE	
PROPYLENE GLYCOL	
SO DIUM BENZO ATE	
SO DIUM PHO SPHATE	
SORBITOL	
SUCRALOSE	
WATER	
FD&C YELLOW NO. 5	

Product Characteristics			
Color	GREEN	Score	
Shape		Size	
Flavor	KIWI	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:41167-0934-0	500 mL in 1 BOTTLE, DISPENSING		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	12/0 1/20 12	

Labeler - Chattem, Inc. (003336013)

Establishment			
Name	Address	ID/FEI	Business Operations
Chattem		0 220 720 21	ANALYSIS(41167-0934), LABEL(41167-0934), MANUFACTURE(41167-0934), PACK(41167-0934),

	10.277.39.31
Plant 3	RECOVERY(41167-0934), RELABEL(41167-0934), REPACK(41167-0934)
I lullt 5	MECO VERT(+1107 0354), REEMBEE(+1107 0354), REIMOR(+1107 0354)

Revised: 3/2013 Chattem, Inc.