

ACT RESTORING ANTICAVITY FLUORIDE MINT BURST- sodium fluoride mouthwash
Chattem, Inc.

ACT Restoring Mint Burst 2x

ACT® Restoring™ Mint Burst
Anticavity Fluoride Rinse

Drug Facts

Active ingredient

Sodium fluoride 0.02% (0.009% 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 twice a day after brushing your teeth with a toothpaste
- remove cap
- pour 10 milliliters into cap (10 mL mark on inside of cap); do not fill above 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

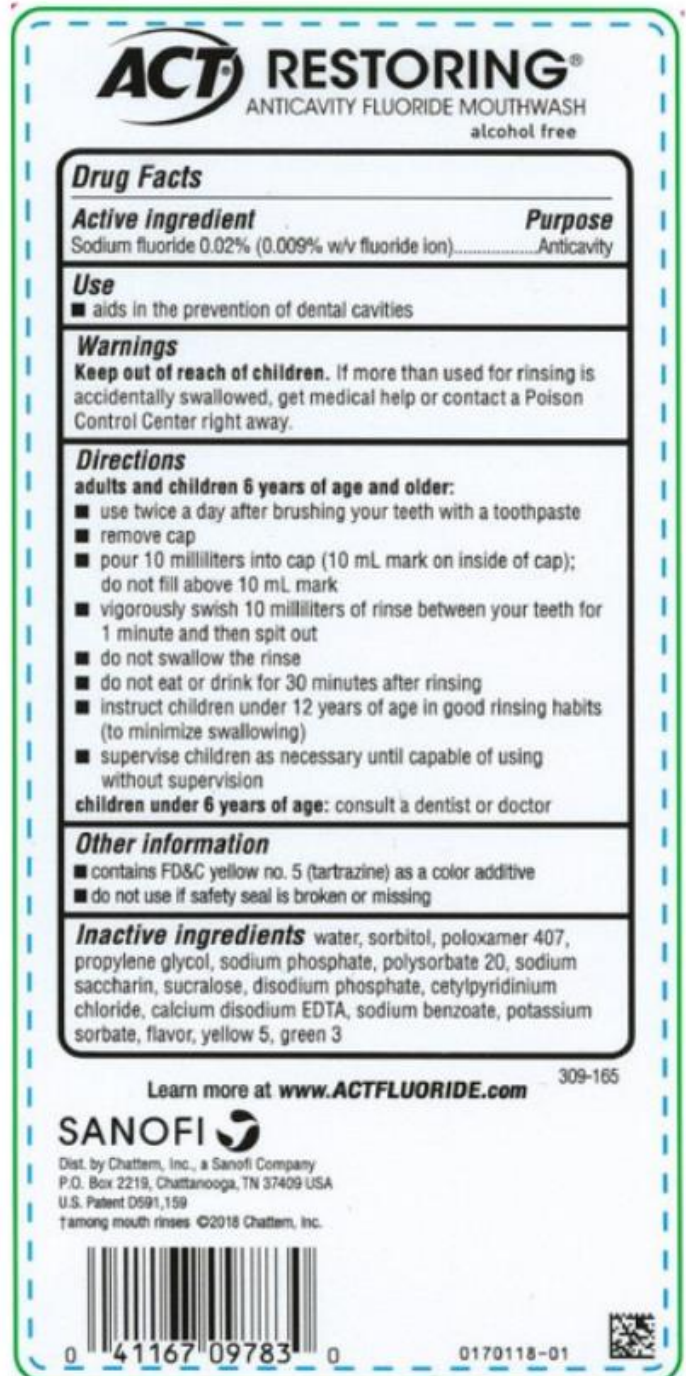
- contains FD&C yellow no. 5 (tartrazine) as a color additive
- do not use if safety seal is broken or missing

Inactive ingredients

water, sorbitol, poloxamer 407, propylene glycol, sodium phosphate, polysorbate 20, sodium saccharin, sucralose, disodium phosphate, cetylpyridinium chloride, calcium disodium EDTA, sodium benzoate, potassium sorbate, flavor, yellow 5, green 3 (309-165)

PRINCIPAL DISPLAY PANEL

ZERO ALCOHOL
#1 DENTIST RECOMMENDED
FLUORIDE BRAND
ACT
2X Daily
RESTORING
ANTICAVITY FLUORIDE MOUTHWASH
MINT BURST
33.8 oz (1 L)



ACT RESTORING ANTICAVITY FLUORIDE MINT BURST

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0978
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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Product Characteristics

Color	green	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0978-3	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/16/2015	
2	NDC:41167-0978-6	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/16/2015	07/07/2018
3	NDC:41167-0978-1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/22/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	12/16/2015	

Labeler - Chattem, Inc. (003336013)