

ACT WHITENING ANTICAVITY GENTLE MINT- sodium fluoride 0.02 (0.009 w/v fluoride ion) mouthwash

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 Whitening Anticavity Fluoride Mouthwash Gentle Mint

ACT Whitening

Anticavity Gentle Mint

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

Stop use and ask a dentist if

oral irritation or tooth sensitivity occurs

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 12 years of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 milliliters (2 teaspoonfuls) 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
- supervise children as necessary until capable of using without supervision

children under 12 years of age: consult a dentist or doctor

Other information

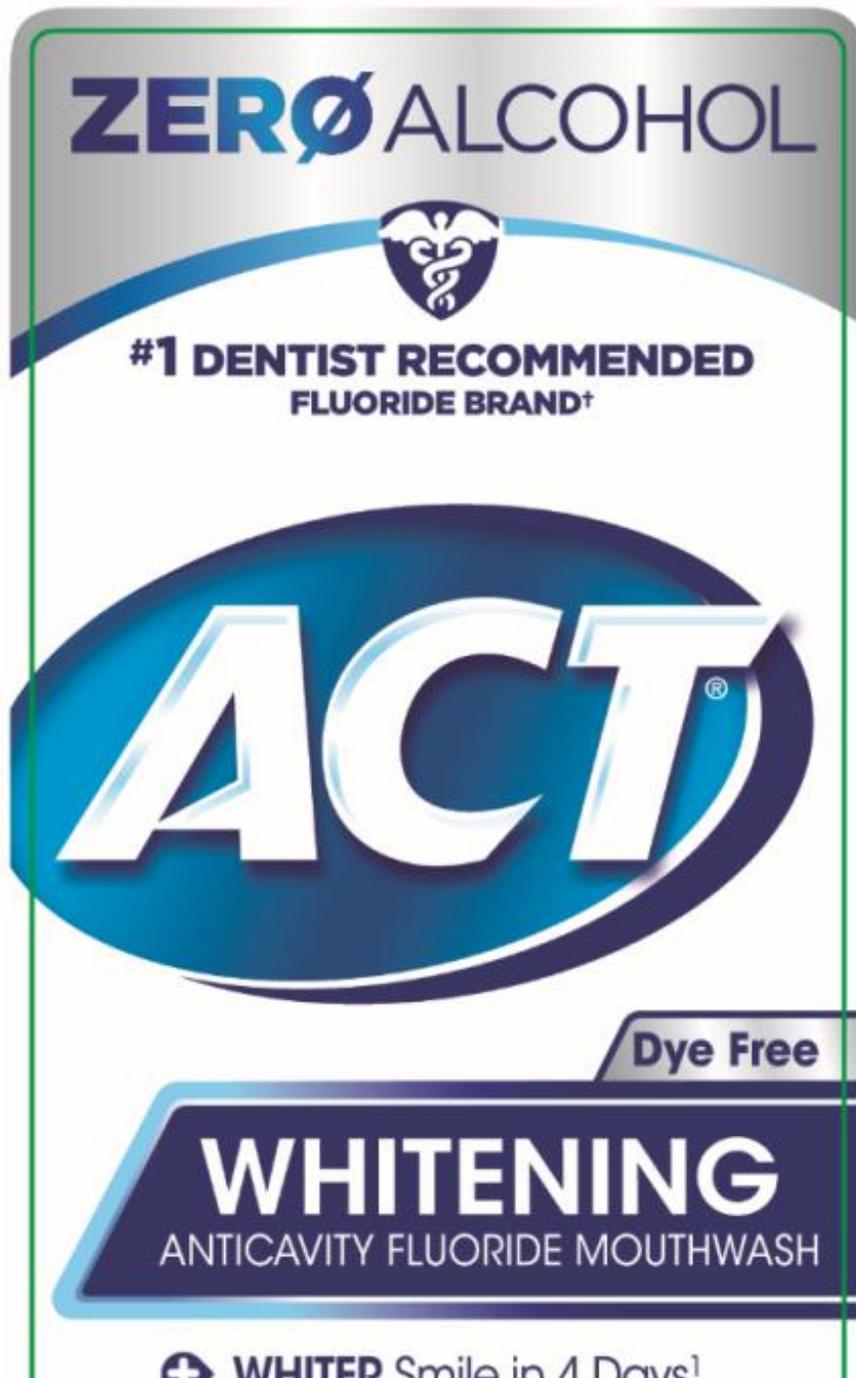
- do not use if safety seal is broken or missing

Inactive ingredients

water, glycerin, xylitol, hydrogen peroxide, poloxamer 407, propylene glycol, pentylene glycol, flavors, sodium benzoate, sodium phosphate, disodium phosphate, 4-t-butylcyclohexanol, menthol, sucralose, sodium saccharin, calcium disodium EDTA

PRINCIPAL DISPLAY PANEL

ACT
WHITENING
ANTICAVITY FLUORIDE MOUTHWASH
GENTLE MINT
16.9 fl oz (500 mL)



- ⊕ WHITENS ORALS in 4 Days
- ⊕ PROMOTES Oral Health²
- ⊕ STRENGTHENS & PROTECTS Teeth
- ⊕ KILLS Bad Breath Germs



GENTLE MINT

Sodium Fluoride 0.02% IMPORTANT: Read directions for proper use.

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0170038-01



ACT[®] WHITENING
 ANTICAVITY FLUORIDE MOUTHWASH
 alcohol free

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333-101

Learn more at www.ACTFLUORIDE.com

SANOFI 

Dist. by Chatterm, Inc., a Sanofi Company
P.O. Box 2219, Chattanooga, TN 37409 USA

*among mouth rinses

†vs Baseline

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ACT WHITENING ANTICAVITY GENTLE MINT

sodium fluoride 0.02 (0.009 w/v fluoride ion) mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0983
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.09 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
4-TERT-BUTYLCYCLOHEXANOL (UNII: K0H1405S9C)	
MENTHOL (UNII: L7T10EIP3A)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

EDETATE CAL CIUM DISODIUM ANHYDRO US (UNII: 8U5D034955)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0983-2	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	03/01/2019	

Labeler - Chattem, Inc. (003336013)

Revised: 3/2019

Chattem, Inc.