

**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**

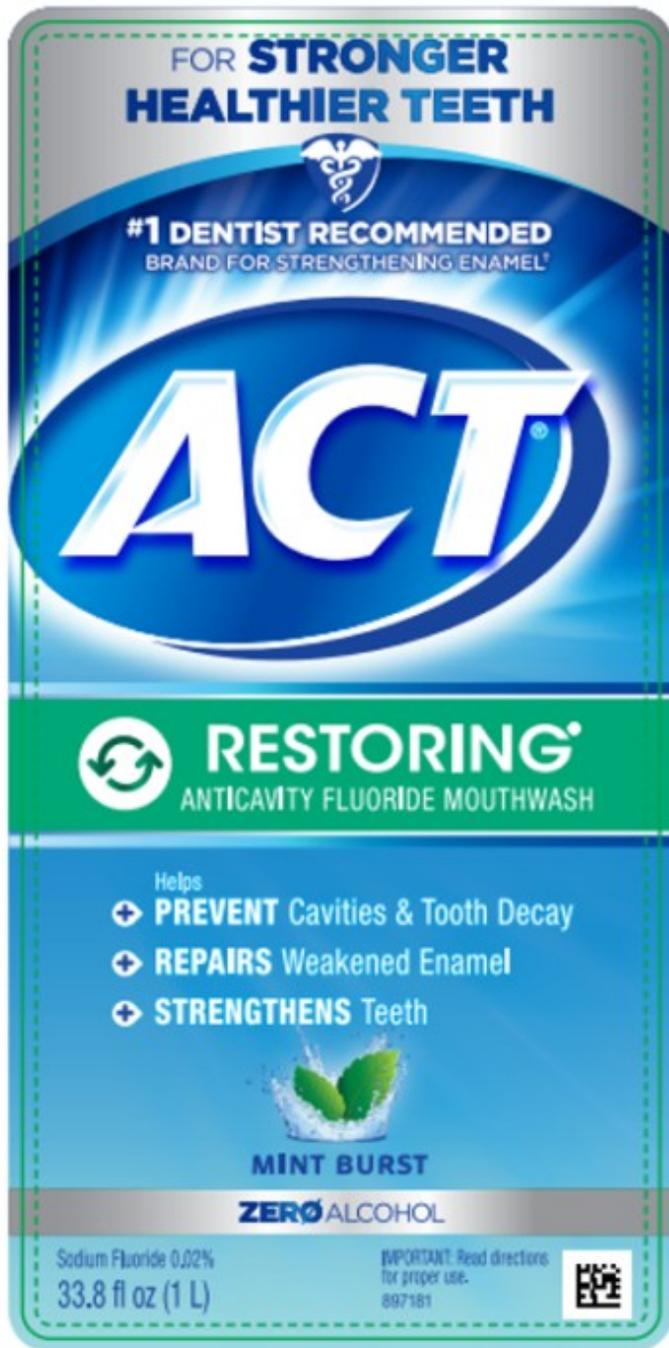
- contains FD&C yellow no. 5 (tartrazine) as a color additive
- do not use if safety seal is broken or missing

**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**

#1 DENTIST RECOMMENDED  
BRAND FOR STRENGTHENING ENAMEL  
ACT  
RESTORING  
ANTICAVITY FLUORIDE MOUTHWASH  
MINT BURST  
33.8 oz (1 L)



## ACT RESTORING ANTICAVITY FLUORIDE MINT BURST

sodium fluoride mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41167-0978
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

## 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)