

## **KIDS ANTICAVITY- kids anticavity mouthwash**

**Vi Jon**

*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.*

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### **Anticavity Fluoride Rinse 004 004.002/004AE**

#### **Active ingredient**

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

#### **Purpose**

Anticavity rinse

#### **Use**

aids in the prevention of dental cavities

#### **Warnings**

for this product

#### **Keep out of reach of children.**

If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

#### **Directions**

- adults and children 6 years of age and older: use once a day after brushing your teeth with a toothpaste.
- remove cap
- pour 10 milliliters (10 mL mark on inside of cap):do not fill above the 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

#### **Inactive ingredients**

benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

#### **claims**

**Sealed With Printed neckband For Your Protection**

"The ADA Council on Scientific Affairs' Acceptance of Swan Anticavity Fluoride Rinse is based on its finding that the product is effective in helping to prevent and reduct tooth decay, when used as directed"

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Act Anticavity Fluoride Rinse.

Distributed by: Vi-Jon, One Swan Drive, Smyrna, TN 37167

004.002/004AE

**principal display panel**

Mountain

falls

Compare to Act

Alcohol

free

helps

strengthen teeth

strong

cavity

protection

for kids

anticavity

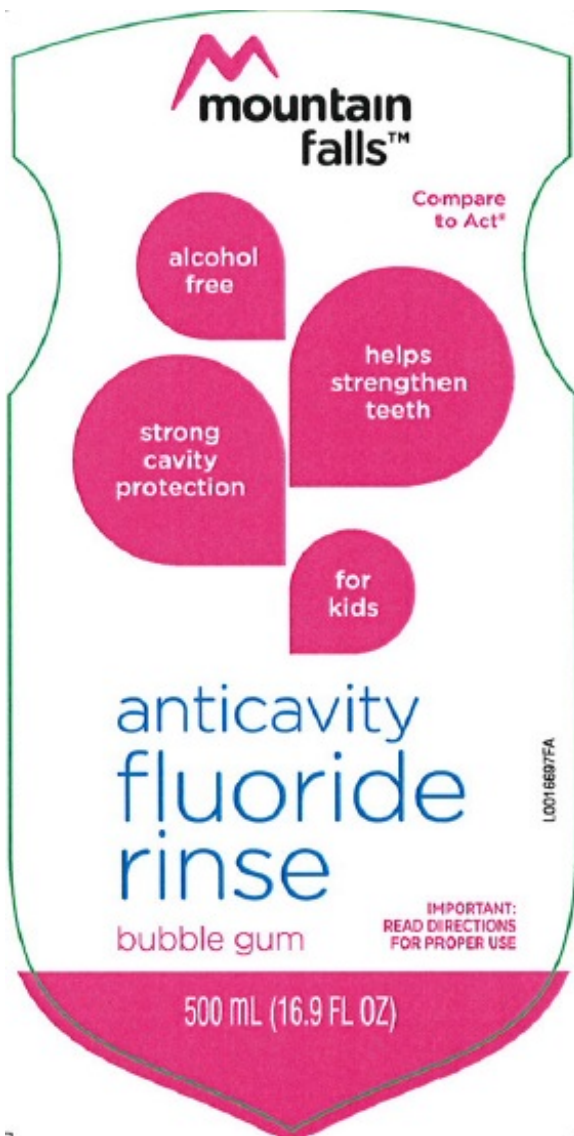
fluoride

rinse

bubble gum

**IMPORTANT: READ DIRECTIONS FOR PROPER USE**

500 mL (16.9 FL OZ)



**principal display panel**

Sealed With Printed Neckband For Your Protection

SWAN

kids

ANTICAVITY

ALCOHOL FREE

FLUORIDE RINSE

bubble gum

FLAVOR

Strong Cavity Protection

Compare to the active ingredient of Bubblegum Blowout Act Anticavity Fluoride Rinse

IMPORTANT:READ DIRECTIONS FOR PROPER USE

ADA

Accepted

American  
Dental  
Association  
18 FL OZ (532 mL)



<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purpose</b>
Sodium fluoride 0.06% (0.02% w/v fluoride ion)...	Anticavity rinse
<b>Use</b> aids in the prevention of dental cavities.	
<b>Warning</b>	
Keep out of reach of children. If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ adults and children 6 years of age and older: use once a day after brushing your teeth with a toothpaste</li> <li>■ remove cap</li> <li>■ pour 10 milliliters (10 ML mark on inside of cap); do not fill above 10 ML mark</li> <li>■ vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out</li> <li>■ do not swallow the rinse</li> <li>■ do not eat or drink for 30 minutes after rinsing</li> <li>■ instruct children under 12 years of age in good rinsing habits (to minimize swallowing)</li> <li>■ supervise children as necessary until capable of using without supervision</li> <li>■ children under 6 years of age: consult a dentist or doctor</li> </ul>	
<b>Inactive ingredients</b> benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polyorbete 80, propylene glycol, red 35, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water	
<b>Other information</b> ■ store at room temperature	

\*The ADA Council on Scientific Affairs' Acceptance of Swans® Anticavity Fluoride Rinse is based on its finding that this product is effective in helping to prevent and reduce tooth decay, when used as directed.

\* This product is not manufactured or distributed by Glaxo, Inc., distributor of Act® Anticavity Fluoride Rinse.

Distributed by: W-Jon, One Swan Drive, Smyrna, TN 37167



L03107746A

## KIDS ANTICAVITY

kids anticavity mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0869-0004
<b>Route of Administration</b>	ORAL		

### 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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

DISODIUM DIHYDROGEN HYPOPHOSPHATE (UNII: MR6TW8IQ9X)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

### Product Characteristics

Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (Bubble Gum Flavor)	Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/06/2004	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/06/2004	

**Labeler** - Vi Jon (790752542)

**Registrant** - Vi Jon (790752542)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon		790752542	manufacture(0869-0004)