

## **ANTICAVITY FLUORIDE RINSE - sodium fluoride mouthwash**

**Geiss, Destin + Dunn, 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.*

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### **Drug Facts**

#### **Active ingredients**

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

#### **Purpose**

Anticavity rinse

Use aids in the prevention of dental cavities

#### **Warning**

**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 the inside of cap); do not fill above the 10 mL mark
- vigorously swish 10 milliliters of rinse between your teeth for 1 minute 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**

- store at room temperature

**Inactive ingredients** benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, green 3, menthol, methyl salicylate, poloxamer 407, polysorbate 20, potassium sorbate, propylene glycol, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water, yellow 5

Sealed With Printed Neckband For Your Protection

GoodSense

**Anticavity**

**Fluoride**

**Rinse**

Strong Cavity Protection

Alcohol Free

**Mint**

ADA

Accepted

American

Dental

Association

**IMPORTANT:**

Read Directions For Proper Use

Compare to active ingredients of

ACT Anticavity Fluoride Rinse

100%  
Satisfaction  
Guaranteed  
18 FL OZ (532 mL)



## ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75981-213
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	.05 kg in 100 L

## Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
MENTHOL (UNII: L7T10EP3A)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75981-213-44	.532 L in 1 BOTTLE, PLASTIC		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/17/2007	

**Labeler** - Geiss, Destin + Dunn, Inc (076059836)

**Registrant** - Vi-Jon (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture

Revised: 4/2011

Geiss, Destin + Dunn, Inc