

**ASSURED ANTICAVITY FLUORIDE KIDS BUBBLEGUM- sodium fluoride rinse
Greenbrier International, 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.

Assured Kids Anticavity Fluoride Rinse Bubblegum

Drug Facts

Active Ingredients

Sodium fluoride 0.05% (Fluoride ion-0.0226%)

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, get medical help 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
- use approximately one tablespoon and rinse vigorously 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
- 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 Phosphate, Flavor, Poloxamer 407, Polysorbate 80, Propylene Glycol, Red 33, Sodium Benzoate, Sodium Phosphate, Sodium Saccharin, Sorbitol, Water

Other information

- Store at room temperature

*Anticavity Fluoride Rinse is not manufactured or distributed by Personal Products Company division or McNeil-PPC., distributor or Act®

DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC.

CHESAPEAKE, VA 23320

MADE IN CANADA

ASSURED™

Compare to ACT® active ingredient*

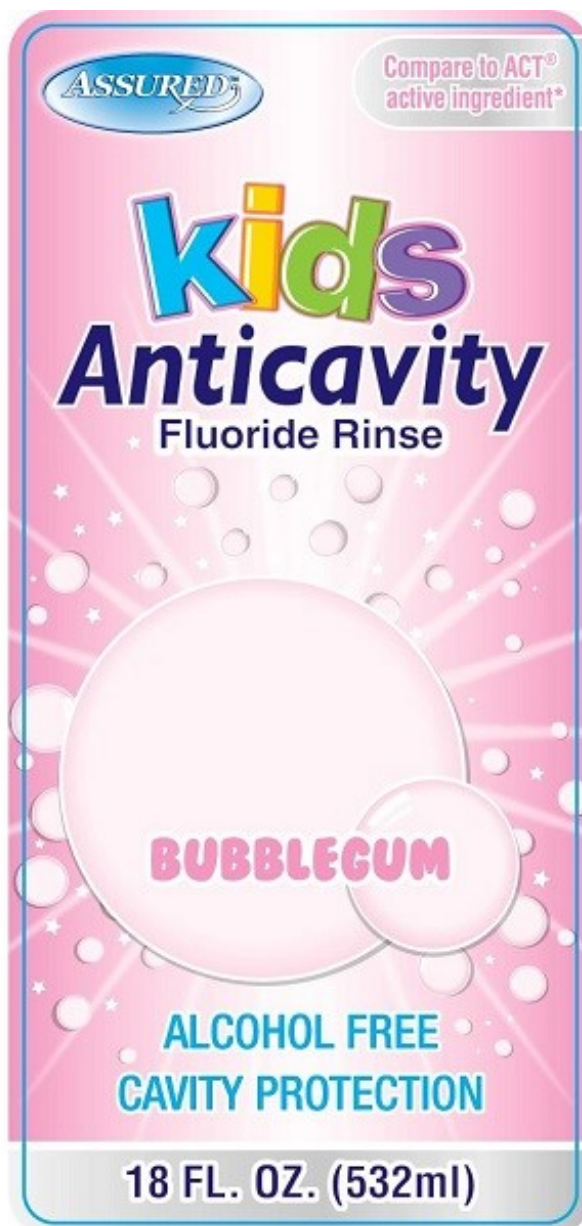
Kids Anticavity

Fluoride Rinse
BUBBLEGUM

ALCOHOL FREE

CAVITY PROTECTION

18 FL. OZ. (532 mL)



Drug Facts	
Active Ingredients	Purpose
Sodium fluoride 0.05%.....Anticavity rinse (Fluoride ion-0.0226%)	
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	
<ul style="list-style-type: none"> ■ adults and children 6 years of age and older, use once a day after brushing your teeth with toothpaste ■ remove cap ■ use approximately one tablespoon and rinse vigorously 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 ■ 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 Phosphate, Flavor, Poloxamer 407, Polysorbate 80, Propylene Glycol, Red 33, Sodium Benzoate, Sodium Phosphate, Sodium Saccharin, Sorbitol, Water.	
Other information	
■ Store at room temperature	
* Anticavity Fluoride Rinse is not manufactured or distributed by Personal Products Company division or McNeil-PPC., distributor of Act®	
DISTRIBUTED BY GREENBRIER INTERNATIONAL, INC. CHESAPEAKE, VA 23320 MADE IN CANADA	
 6 39277 88261 5	

ASSURED ANTICAVITY FLUORIDE KIDS BUBBLEGUM

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:33992-0015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE (UNII: SE337SVY37)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM45K49P)	
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 DIBASIC DIHYDRATE (UNII: 9425516E2T)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0015-7	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2010	

Labeler - Greenbrier International, Inc. (610322518)