

ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid
Meijer Distribution, 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.

Drug Facts

Claims

Sealed with printed neckband for your protection

Claims

Promotes fresh breath while fighting cavities

Alcohol-free formula will not burn as it helps kill germs

Active ingredients

Active Ingredient

Sodium fluoride 1.1219% (0.0 w/v fluoride ion)

Purpose

Purpose

Anticavity

Use

Use aids in the prevention of dental cavities

Warning

Warning

Keep out of reach of children

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

Directions

Adults and children 6 years of age and older:

- use twice daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL (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
- 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

Inactive ingredients water, glycerin, flavor, cetylpyridinium chloride, phosphoric acid, methylparaben, sodium saccharin, poloxamer 407, propylparaben, propylene glycol, disodium phosphate, red 33, green3

Claims

This rinse may cause temporary staining to the surface of teeth. This is not harmful, and adequate brushing may prevent its occurrence.

Disclaimer

This product is not manufactured or distributed by Procter + Gamble, distributor of Crest Pro-Health Complete Anticavity Fluoride Rinse.

Adverse Reaction

DISTRIBUTED BY

MEIJER DISTRIBUTION, INC.

2929 WALKER AVE NW

GRAND RAPIDS, MI 49544

www.meijer.com

Principal Display panel

Meijer

Alcohol-Free

ANTICAVITY

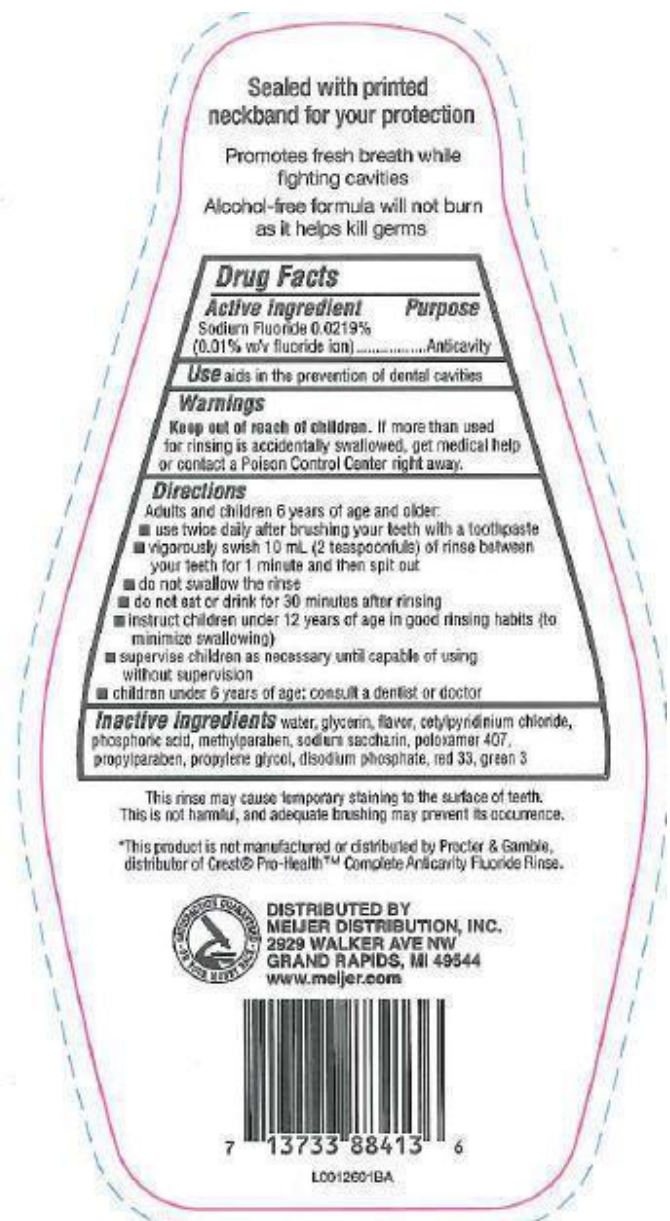
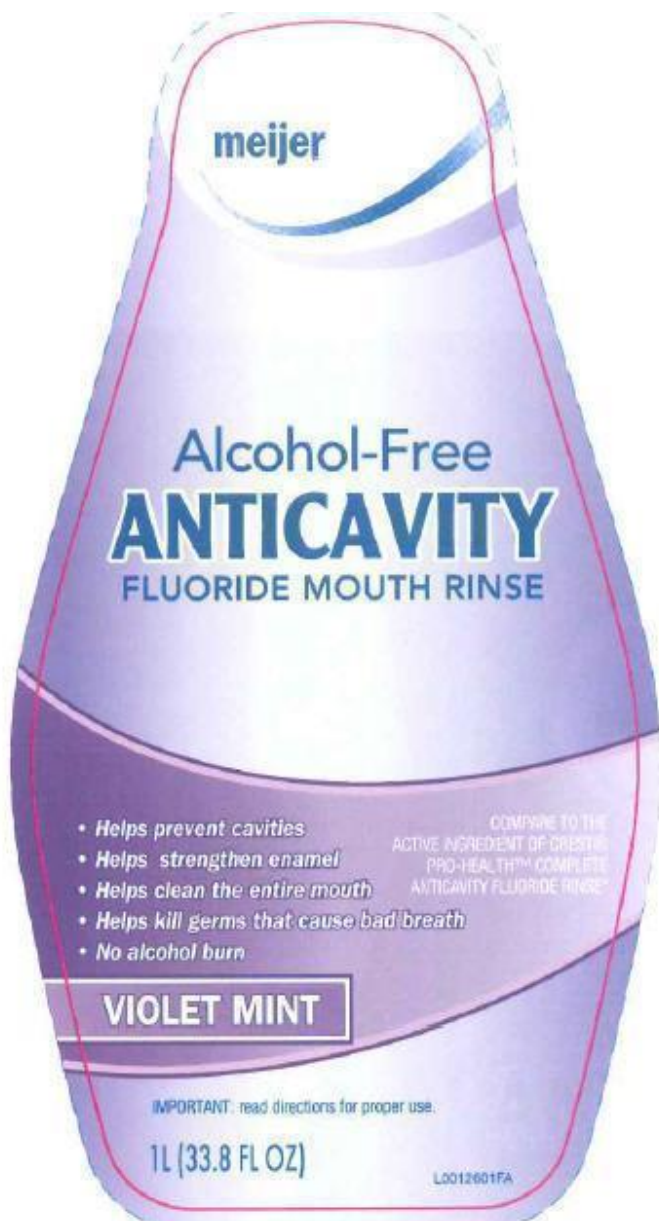
FLUORIDE MOUTH RINSE

- Helps prevent cavities
- Helps strengthen enamel
- Helps clean the entire mouth
- Helps kill germs that cause bad breath
- No alcohol burn

VIOLET MINT

IMPORTANT: read directions for proper use

1 L (33.8 FL OZ)



ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-482
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SACCHARIN SODIUM DIHYDRATE (UNII: SB8ZUX40TY)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-482-86	1000 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/22/2012	

Labeler - Meijer Distribution, Inc (006959555)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(41250-482)

Revised: 10/2012

Meijer Distribution, Inc