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 preveiontion of dental cavities

Warning

Warning

Keep out of reach of children

Keep our 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 occurence.

Dis lcaimer

Ths 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

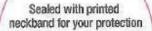
- Helps prevent cavities
- Helps strengthen enamel
- Helps clean the entire mouth
- Helps kiss germs that cause bad breath
- No alcohol burn

VIOLET MINT

IMPORTANT: read directiosn for proper use

1 L (33.8 FL OZ)





Promotes fresh breath while fighting cavities Alcohol-free formula will not burn

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Drug Facts

Active ingredient Sodiem Fluoride 0.0219% (0.01% w/v fluoride ion).....

Purpose

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Warnings

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ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product Information

Product Type HUMAN OTC DRUG LABEL Item Code (Source)

NDC:41250-482

Route of Administration

ORAL

DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength SODIUM FLUORIDE (FLUORIDE ION) FLUORIDE ION 0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name

Strength

water

GLYCERIN	
CETYLPYRIDINIUM CHLO RIDE	
PHO SPHO RIC ACID	
METHYLPARABEN	
SACCHARIN SO DIUM DIHYDRATE	
POLOXAMER 407	
PROPYLPARABEN	
PROPYLENE GLYCOL	
SO DIUM PHO SPHATE, DIBASIC, ANHYDRO US	
D&C RED NO. 33	
FD&C GREEN NO. 3	

ı	Packaging	nckaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	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