ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid Target Corporation

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.

UP & UP Anticavity Fluoride Rinse 482.001/482AB

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

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

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 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

water, glycerin, cetylpyridinium chloride, flavor, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, red 33, green 3

Questions or comments

1-800-910-6874

This rinse may cause temporary staining to the surface of teeth. This is not harmful, and adequate burshing may prevent it occurence.

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

Distributed by Target Corporation

Minneapolis, MN 55403

Made in the U.S.A. with U.S. and foreign components

principal display panel

SEALED WTIH PRINTED NECKBAND FOR YOUR PROTECTION

anticavity

alcohol-free fluoride mouth rinse

Compare to the active ingredient in Crest Advanced*

helps prevent cavities

helps make enamel stronger

helps clean the entire mouth

freshens breath

no alcohol burn

IMPORTANT: read directions for proper use

up & up

MINT FLAVOR

33.8 FL OZ (1 L)



ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

Product I	nformation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-482

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 0.1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
water (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

I	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
	1	NDC:11673- 482-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/09/2012	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/09/2012	

Labeler - Target Corporation (006961700)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11673-482)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11673-482)

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