

## **ALCOHOL-FREE ANTICAVITY- sodium fluoride liquid**

**Walgreen Co**

*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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### **Anticavity Fluoride Rinse**

**482**

#### **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, flavor, cetylpyridinium chloride, phosphoric acid, methylparaben, sodium saccharin, poloxamer 407, propylparaben, propylene glycol, disodium phosphate, red 33, green 3

#### **Questions**

Call 1-888-593-0593

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

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

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

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

**Principal Display Panel**

**SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION**

Well at Walgreens

ANTICAVITY FLUORIDE

Mouth rinse

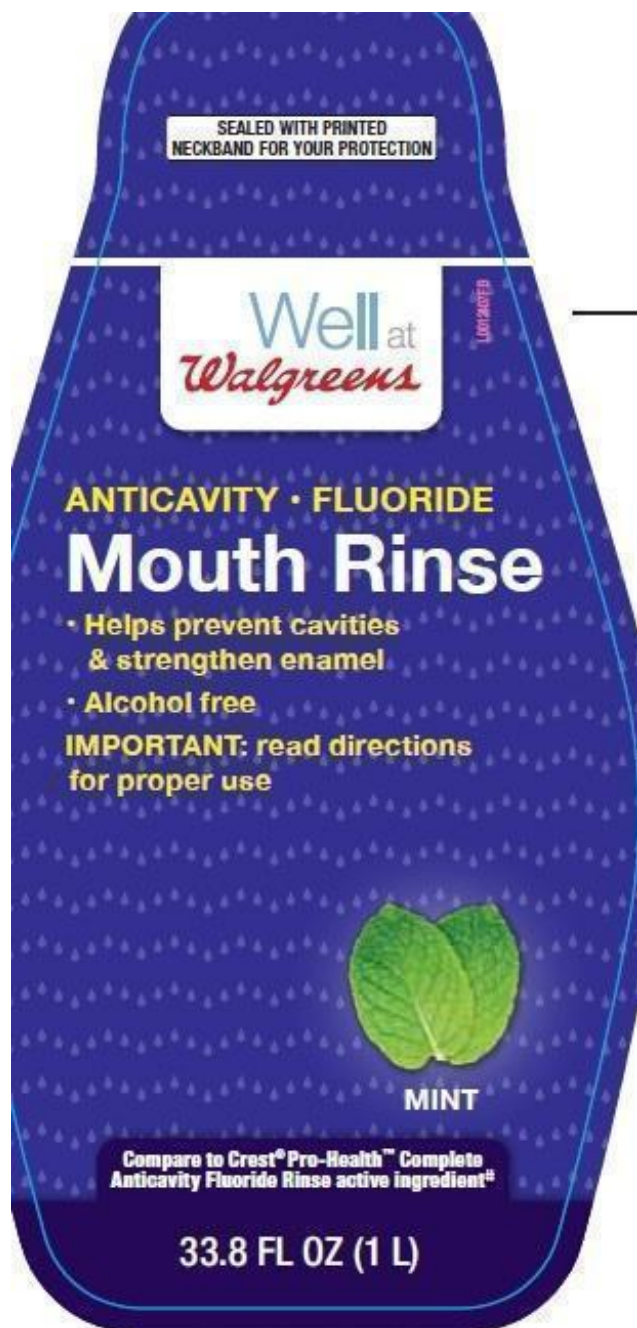
- Helps prevent cavities + strengthen enamel
- Alcohol free

IMPORTANT: read directions for proper use

MINT

Compare to Crest Pro-Health Complete Anticavity Fluoride Rinse active ingredient

33.8 FL OZ (1 L)



482.000/482AA

## ALCOHOL-FREE ANTICAVITY

sodium fluoride liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0482
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)				
CETYL PYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
METHYL PARABEN (UNII: A2I8C7H9T)				
SACCHARIN SODIUM (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:0363-0482-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/01/2013	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355		06/01/2013	

**Labeler** - Walgreen Co (008965063)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(0363-0482)