

ANTICAVITY FLUORIDE- sodium fluoride mouthwash

CVS Pharmacy

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.

Anticavity Fluoride Mouthwash Minty Fresh

Drug Facts

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 a day 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 12 years of age in good rinsing habits (to minimize swallowing).

Supervise children as necessary until capable of using without supervision.

Close cap fully after use, until the cap is felt to “click”, to reengage the child resistant cap.

Children under 6 years of age: Consult a dentist or doctor

Other information Store at room temperature. Cold temperature may temporarily cloud this product.

Inactive ingredients

water, sorbitol, propylene glycol, poloxamer 407, phosphoric acid, sodium lauryl sulfate, sodium saccharin, disodium phosphate, sucralose, eucalyptol, sodium benzoate, thymol, methyl salicylate, flavor, menthol, red 40, blue 1.

This rinse may cause temporary staining to the surface of teeth.

This is not harmful and adequate brushing may prevent its occurrence.

PRINCIPAL DISPLAY PANEL

Anticavity Fluoride

Mouthwash

Sodium Fluoride Oral Solution

Minty Fresh

1 L (33.8 FL OZ)



ANTICAVITY FLUORIDE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-232
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)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
EUCALYPTOL (UNII: RV6J6604TK)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
THYMOL (UNII: 3J50XA376E)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MENTHOL (UNII: L7T10EIP3A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-232-15	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/30/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	01/30/2017	

Labeler - CVS Pharmacy (062312574)

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