SODIUM FLUORIDE- sodium fluoride rinse
Vi-Jon

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.

971.001 971AB
Fluoride Anti-Cavity Mouthwash

Active Ingredient

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

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warning

for this product

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately

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 miute 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

Other information

- store at room temperature 20□-25□ C (68□-77□ F)
- cold weather may temporarily cloud this product

Inactive ingredients

water, sorbitol solution, propylene glycol, flavor, sodium lauryl sulfate, poloxamer 407, sodium benzoate, phosphoric acid, sodium saccharin, disodium phosphate, sucralose, red 40, blue 1

principal display panel

Anticavity Mouthwash

IMPORTANT: Read directions for proper use.

33.8 FL OZ (1 L)

971.000/971AA

Image not available.
Manufactured exclusively for private label distribution

VI·JON®

SODIUM FLUORIDE

sodium fluoride rinse

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0869-0971
Route of Administration	Oral		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
water (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0971-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/11/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	02/11/2013	

Labeler - Vi-Jon (790752542)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(0869-0971)

Revised: 10/2020 Vi-Jon