

ORAL ANTICAVITY- sodium fluoride mouthwash

Rite Aid

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.

Alcohol Free Fluoride Refreshing Mint Mouthwash

576.001/576AC-AD

MULTI-ACTION

with FLUORIDE

ALCOHOL FREE

MOUTHWASH

ANTICAVITY FLUORIDE MOUTHRINSE

active ingredient

Sodium fluoride 0.02%

(0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warnings

for this product

Keep out or 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 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, sodium saccharin, phosphoric acid, sodium benzoate, sucralose, poloxamer 407, benzoic acid, disodium phosphate, propylene glycol, blue 1

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 Advanced Anticavity Fluoride Mouthwash

**This product is not intended to replace brushing or flossing

DISTRIBUTED BY: RITE AID,

30 HUNTER LANE,

CAMP HILL, PA 17011

www.riteaid.com

SATISFACTION GUARANTEE

If you're not satisfied, we'll happily refund your money.

principal panel display

Sealed with printed neckband for your protection

Compare to Crest[®] Pro-Health[™] Advanced Anticavity Fluoride Mouthwash*

FREE FROM

ALCOHOL FREE

PARABEN FREE

MULTI-ACTION

WITH FLUORIDE

ALCOHOL FREE

MOUTHWASH

ANTICAVITY FLUORIDE MOUTHRINSE

REFRESHING MINT

6 BENEFITS

kills bad breath

helps prevent cavities

helps strengthen enamel

cleans teeth**

leaves mouth feeling clean

IMPORTANT:

read directions for proper use.

1L (33.8 FL OZ)



ORAL ANTIVAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-5768
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)			FLUORIDE ION	0.2 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: 8SKN0B0MIM)				
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
propylene glycol (UNII: 6DC9Q167V3)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-5768-6	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/05/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355		12/05/2022	

Labeler - Rite Aid (014578892)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11822-5768)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11822-5768)