ANTICAVITY FLUORIDE RINSE- 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.

Drug Facts

Active ingredient

Sodium fluoride 0.0221% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities

Warning

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 12 years of age and older:

- use twice daily after brushing your teeth with 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 12 years of age: consult a dentist or doctor

Other information

- store at controlled room temperature 200 -250 C (680 770 F)
- cold weather may temporarily cloud this product

Inactive ingredients

water, alcohol (21.6%), sorbitol, poloxamer 407, sodium lauryl sulfate, eucalyptol, flavor, methyl salicylate, thymol, phosphoric acid, sucralose, menthol, disosium phosphate, red 40, blue 1

*This product is not manufactured or distributed by Johnson + Johnson Healthcare Products, distributor of Listerine Total Care Anticavity Mouthwash

DISTRIBUTED BY:

RITE AID

30 Hunter Lane, Camp Hill, PA 17011

DSP-TN-1500

DSP-MO-34 SDS-TN-15012

Principal Display Panel

RITE AID PHARMACY Sealed With Printed Neckband For Your Protection IMPORTANT: READ DIRECTIONS FOR PROPER USE *Compare to the active ingredient in Listerine Total Care Anticavity Mouthwash Anticavity Mouthwash Sodium Fluoride and Acidulated Phosphate Topical Solution fresh mint helps prevent cavities restores enamel helps strengthen teeth helps kill bad breath germs leaves the mouth feeling clean

1 LITER (33.8 FL OZ)



Sealed With Printed Neckband For Your Protection IMPORTANT: READ DIRECTIONS FOR PROPER USE

*Compare to the active ingredient in Listerine® Total Care Anticavity Mouthwash

anticavity mouthwash Sodium Fluoride and Acidulated Phosphate Topical Solution

Multi Benefits In One

helps prevent cavities restores enamel helps strengthen teeth helps kill bad breath germs freshens breath leaves the mouth feeling clean

fresh mint

LITER (33.8 FL 0Z)

ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

L0015490FA

Route of Administration

Product Type

ORAL

HUMAN OTC DRUG

Item Code (Source)

NDC:11822-3705

A	Terreral			№
Active	Ingred	ient/Ac	rtive	Molety

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)					
ALCOHOL (UNII: 3K9958V90M)					
SORBITOL (UNII: 506T60A25R)					
POLOXAMER 407 (UNII: TUF2IVW3M2)					
SODIUM LAURYL SULFATE (UNII: 368GB5141J)					
EUCALYPTOL (UNII: RV6J6604TK)					
METHYL SALICYLATE (UNII: LAV5U5022Y)					
THYMOL (UNII: 3J50XA376E)					

P	PHO SPHO RIC ACID (UNII: E4GA8884NN)						
sı	icralose (UNII: 96)	K6 UQ	3ZD4)				
Μ	IENTHOL (UNII: L	7T10 E	IP3A)				
S	O DIUM PHO SPHA	ATE, D	IBASIC, ANHYDROUS (UNII: 22ADO53M6F)				
F	D&C RED NO.40	(UNII:	WZB9127XOA)				
F	D&C BLUE NO.1	(UNII:	H3R47K3TBD)				
P	ackaging						
#	Item Code		Package Description		Marketing Start Date	N	farketing End Date
# 1	Item Code NDC:11822- 3705-4	1000 Pro du	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	n	-	N	-
#	NDC:11822-		mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	n	-	N	-
#	NDC:11822-		mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	n	-	N	-
1	NDC:11822-	Pro du	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	n	-	N	-
1	NDC:11822- 3705-4	Produ nfor	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination		-		-
1 N N	NDC:11822- 3705-4 Marketing In	Produ nfor ory	mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination act mation Application Number or Monograph Citation	Mar	Date		Date

Labeler - Rite Aid (014578892)

Registrant - Vi Jon (790752542)

Establishment						
Name	Address	ID/FEI	Business Operations			
Vi Jon		790752542	manufacture(11822-3705)			

Revised: 2/2016

Rite Aid