

SODIUM FLUORIDE- sodium fluoride solution

Target Corp.

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.

Whitening Anticavity Mouth Rinse

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 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, alcohol (8%), hydrogen peroxide, poloxamer 407, sodium saccharin, sucralose, menthol, phosphoric acid, disodium phosphate, flavor

Other information

store at room temperature (59°-77°F)

Disclaimer

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine HealthyWhite Anticavity Mouthrinse

Principal Display Panel

SAFETY SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

IMPORTANT: read directions for proper use

Whitening

Anticavity mouth rinse

Begins working on contact

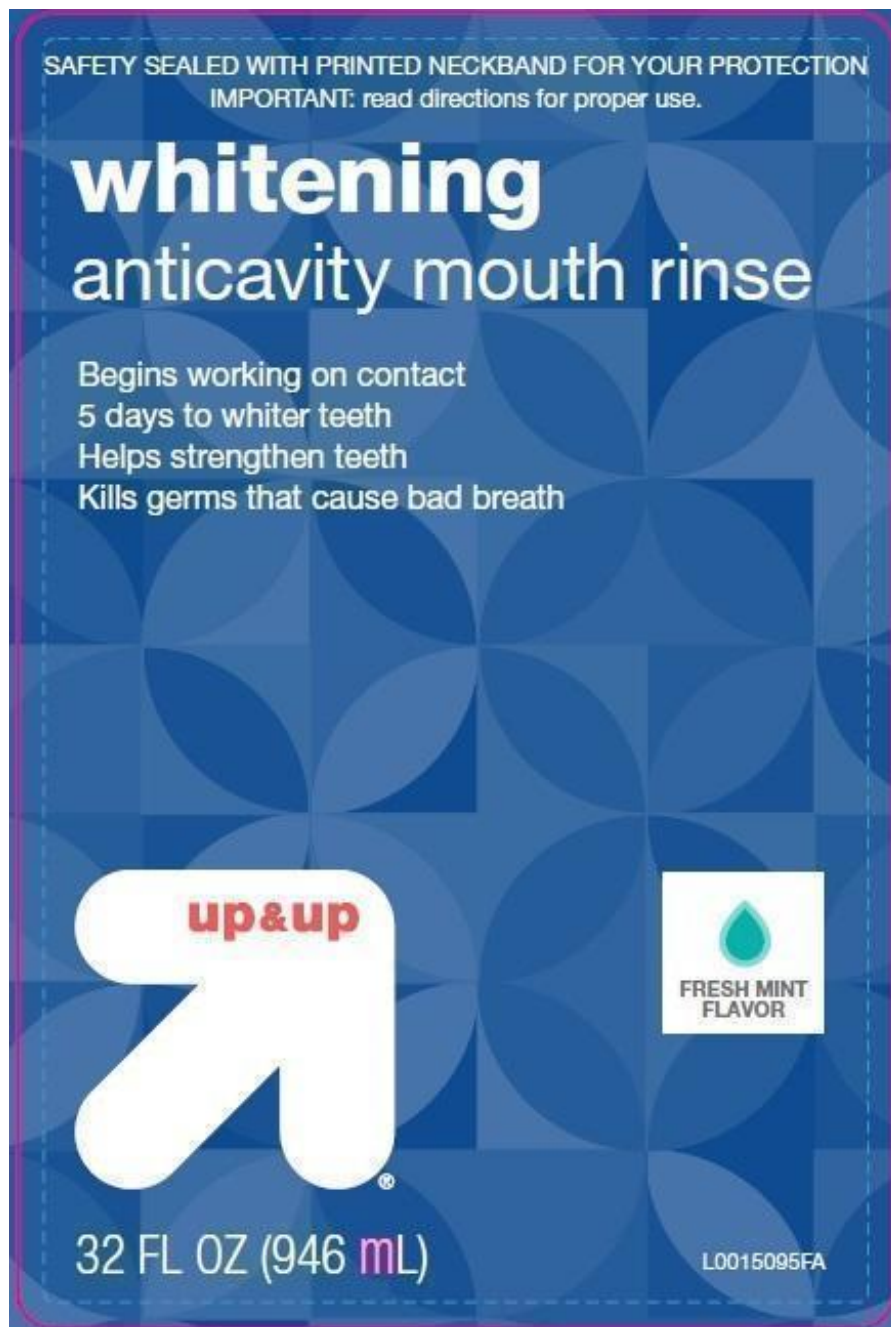
5 days to whiter teeth

Helps strengthen teeth

Kills germs that cause bad breath

Fresh mint flavor

32 fl oz (946 mL)



SODIUM FLUORIDE

sodium fluoride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-435
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
MENTHOL (UNII: L7T10EIP3A)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SODIUM PHOSPHATE, DIBASIC ANHYDROUS (UNII: 22ADO53M6F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-435-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/28/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/28/2015	

Labeler - Target Corp. (006961700)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, Inc.		790752542	manufacture(11673-435) , analysis(11673-435)