

GLOWING WHITE- sodium fluoride mouthwash
Demoulas Super Markets, Inc

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.

Market Basket 435.000 435AA

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 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 Vibrant Anticavity Mouthrinse

Contains peroxide which releases oxygen while whitening. This may cause the bottle to inflate slightly or release air when opened

Adverse Reactions

DISTRIBUTED BY

DEMOULAS SUPER MARKETS, INC.

875 East Street

Tewksbury, MA 01876

principal display panel

MORE FOR YOUR DOLLAR

MARKET BASKET

Compare to Listerine HealthyWhite Vibrant
Anticavity Mouthrinse

GLOWING WHITE

ANTICAVITY

MOUTHRINSE

Fresh Mint

Begins working on contact

5 days to whiter teeth

Helps strengthen teeth

Kills germs that cause bad breath

Sealed With Printed Neckband For Your Protection

IMPORTANT: read directions for proper use

32 FL OZ (946 mL)

"MORE FOR YOUR DOLLAR"

MARKET BASKET

Compare to Listerine®
HealthyWhite™ Vibrant
Anticavity Mouthrinse

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ANTICAVITY
MOUTHRINSE**

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32 FL OZ (946 mL)

L0015083FA

GLOWING WHITE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53942-435
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)				
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, MONOHYDRATE (UNII: BWZ7K44R51)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53942-435-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/29/2015	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	07/29/2015		

Labeler - Demoulas Super Markets, Inc (007869647)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(53942-435)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(53942-435)