

ANTICAVITY - sodium fluoride mouthwash

Onpoint, 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.

Drug Facts

Active ingredients

Sodium fluoride 0.221%(0.021% 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 12 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 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- 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 20° - 25° C (68° - 77°F)
- cold weather may temporarily cloud this product

Inactive ingredients water, sorbitol solution; alcohol (21.6%), flavors, poloxamer 407, sodium lauryl sulfate, phosphoric acid, sucralose and /or sodium saccharin, dibasic sodium phosphate, D+C red no.33, FD+C blue no.1, FD+C yellow no.6

This product is not manufactured or distributed by Johnson + Johnson Healthcare products, distributor of Listerine Total Care

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

DISTRIBUTED BY

ONPOINT, INC

2 PARAGON DRIVE

MONTVALE, NJ 07645

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Live Better

Anticavity

Mouthwash

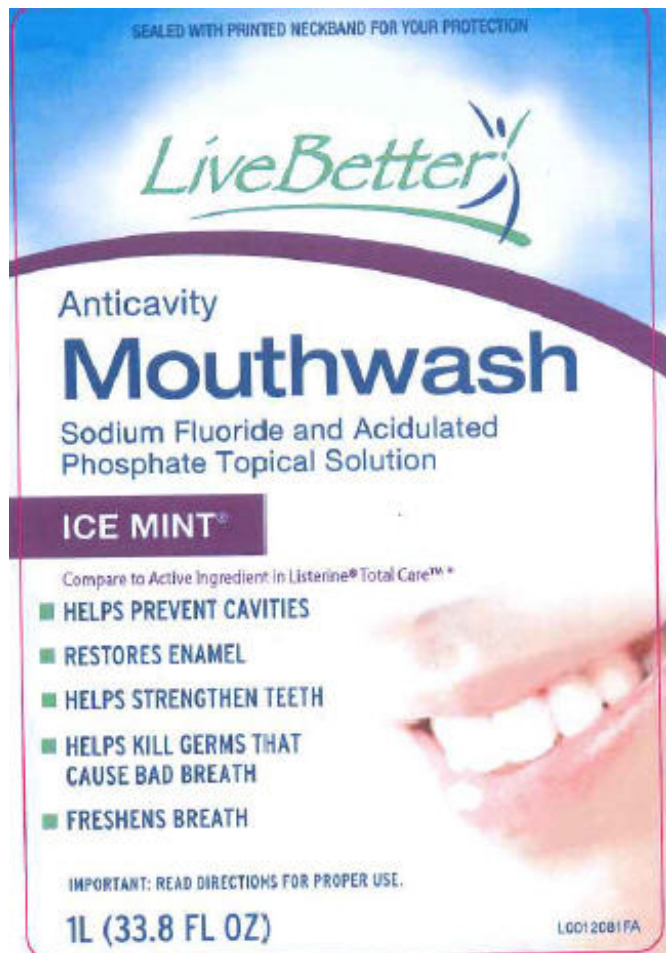
Sodium Fluoride and Acidulated

Phosphate Topical Solution

ICE MINT

Compare to Active Ingredients in Listerine Total Care

- HELPS PREVENT CAVITIES
 - RESTORES ENAMEL
 - HELPS STRENGTHEN TEETH
 - HELPS KILL GERMS THAT CAUSE BAD BREATH
 - FRESHENS BREATH
- IMPORTANT: READ DIRECTIONS FOR PROPER USE.
1L (33.8 FL OZ)



ANTICAVITY

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51143-966
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	.0221 mL in 100 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ALCOHOL (UNII: 3K9958V90M)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51143-966-86	1 L in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/21/2012	

Labeler - Onpoint, Inc (001367366)

Registrant - Vi-Jon (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture

Revised: 3/2012

Onpoint, Inc