

LISTERINE SMART RINSE ANTICAVITY RINSE - FROZEN BUBBLE BLAST- sodium fluoride mouthwash

Johnson & Johnson Consumer 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.

LISTERINE® SMART RINSE® ANTICAVITY FLUORIDE RINSE Disney FROZEN BUBBLE BLAST®

Drug Facts

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 daily after brushing your teeth with a toothpaste
 - remove cap and hold bottle upright. Fill to 10 mL line by squeezing the front and back (not the sides) of the bottle. Pour in a cup.
 - vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out
 - do not swallow the rinse
 - replace cap promptly after use
 - 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

Other information

- store at room temperature
- do not use if printed band around cap is broken or missing

Inactive ingredients

water, sorbitol, flavor, phosphoric acid, sucralose, cetylpyridinium chloride, disodium phosphate, sodium saccharin, menthol, blue 1, green 3

Questions?

call toll-free **888-222-0182** or **215-273-8755** (collect)

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

LISTERINE®

SMART RINSE®

ANTICAVITY
FLUORIDE RINSE

Disney
FROZEN
As seen in
FROZEN
FEVER

Helps Prevent Cavities

**Removes Particles
Brushing May Miss**

BUBBLE BLAST

IMPORTANT: Read
directions for proper use.

**ADA
ACCEPTED
American
Dental
Association®**

**BUBBLE
BLAST®**

500 mL (16.9 fl oz)



Alcohol Free

LISTERINE® SMART RINSE® is an anticavity mouthwash that helps protect teeth. It also cleans the mouth beyond brushing alone:

- Helps prevent cavities even in hard to reach places that brushing may miss
- Cleans by removing food particles and debris, for fresh breath and a clean mouth feeling
- Tints food particles and debris, leaving proof in the sink of a cleaner mouth

© Disney
Visit the Disney website at www.Disney.com/Frozen

The ADA Council on Scientific Affairs' acceptance of LISTERINE® SMART RINSE® Anticavity Fluoride Rinse is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed.

| Drug Facts | |
|---|---|
| Active ingredient | Purpose |
| Sodium fluoride 0.02% (0.01% w/v fluoride ion) | 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 | |
| <ul style="list-style-type: none"> • Adults and children 6 years of age and older: • use twice daily after brushing your teeth with a toothpaste • remove cap and hold bottle upright. Fill to 10 mL line by squeezing the front and back (not the sides) of the bottle. Pour in a cup. • vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out • do not swallow the rinse • replace cap promptly after use • 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 | |



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sodium fluoride mouthwash

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69968-0276 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| sodium fluoride (UNII: 8ZYQ1474W7) (fluoride ion - UNII:Q80VPU408O) | fluoride ion | 0.1 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| water (UNII: 059QF0KO0R) | |
| sorbitol (UNII: 506T60A25R) | |
| phosphoric acid (UNII: E4GA8884NN) | |
| sucralose (UNII: 96K6UQ3ZD4) | |
| cetylpyridinium chloride (UNII: D9OM4SK49P) | |
| sodium phosphate, dibasic, anhydrous (UNII: 22ADO53M6F) | |
| saccharin sodium (UNII: SB8ZUX40TY) | |
| fd&c blue no. 1 (UNII: H3R47K3TBD) | |
| fd&c green no. 3 (UNII: 3P3ONR6O1S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:69968-0276-5 | 500 mL in 1 BOTTLE; Type 4: Device Coated/Impregnated/Otherwise Combined with Drug | 01/01/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC MONOGRAPH FINAL | part355 | 01/01/2011 | |

Labeler - Johnson & Johnson Consumer Inc. (002347102)

Revised: 5/2020

Johnson & Johnson Consumer Inc.