

LISTERINE SMART RINSE BERRY SPLASH- 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[®] BERRY SPLASH

Drug Facts

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity

Use

aids in 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
- remove cap and hold bottle upright. Fill to 10 mL line by squeezing the front and back (not the sides) of the bottle. Stop squeezing. Excess liquid will drain back into the bottle. Pour in the 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

Inactive ingredients

water, sorbitol, flavor, phosphoric acid, cetylpyridinium chloride, sucralose, sodium saccharin, disodium phosphate, red 33, green 3

Questions?

call toll-free **888-222-0182** or **215-273-8755** (collect). www.listerine.com

Distributed by: **JOHNSON & JOHNSON CONSUMER INC.**
Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 500 mL Bottle Label

NEW!

2X STRONGER TEETH

FOR BETTER CAVITY PROTECTION*

ANTICAVITY FLUORIDE RINSE

LISTERINE®

SMART RINSE®

SODIUM FLUORIDE & ACIDULATED PHOSPHATE TOPICAL SOLUTION

ALCOHOL FREE

*Versus brushing alone,
In a lab study.
IMPORTANT: Read
directions for proper use.

ADA

Accepted

American

Dental

Association®

BERRY

SLASH

500 mL (16.9 fl oz)

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30044660



**BERRY
SPLASH**

500 ml (16.9 fl oz)

Alcohol Free

LISTERINE® SMART RINSE® is an anticavity mouthwash that helps protect and strengthen 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



Helps prevent cavities

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sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69968-0606
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0606-5	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/06/2020	09/08/2022
2	NDC:69968-0606-3	27 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/06/2020	

Labeler - Johnson & Johnson Consumer Inc. (118772437)

Revised: 1/2023

Johnson & Johnson Consumer Inc.