

**LISTERINE ESSENTIAL CARE- sodium monofluorophosphate gel, dentifrice**  
Kenvue Brands LLC

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**LISTERINE<sup>®</sup> ESSENTIAL CARE<sup>®</sup> GEL**

***Drug Facts***

**Active ingredient**

Sodium monofluorophosphate 0.76% (0.13% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

aids in the prevention of dental cavities

**Warnings**

**Keep out of reach of children under 6 years of age.** If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- adults and children 2 years of age and older: brush teeth thoroughly, preferably after each meal or at least 2 times a day, or as directed by a dentist or physician.
  - children 2-6 years use a pea sized amount
  - instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing)
  - supervise children as necessary until capable of using without supervision.
- children under 2 years of age: ask a dentist or doctor

**Other information**

- Store at Room Temperature.

**Inactive ingredients**

water, sorbitol, hydrated silica, glycerin, PEG-32, sodium lauryl sulfate, cellulose gum, sodium saccharin, eucalyptol, methyl salicylate, thymol, phosphoric acid, menthol, sodium phosphate, xanthan gum, benzoic acid, flavor, mentha viridis (spearmint) leaf oil, disodium phosphate, blue 1, yellow 10

## **Questions?**

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

Distributed by: Kenvue Brands LLC, Summit, NJ 07901

## **PRINCIPAL DISPLAY PANEL - 119 g Tube Carton**

**LISTERINE®**

**ESSENTIAL CARE®**

FLUORIDE ANTICAVITY TOOTHPASTE

**ORIGINAL GEL**

- **FRESHENS BREATH**
- **THE LISTERINE® WAY**

**POWERFULL MINT GEL**

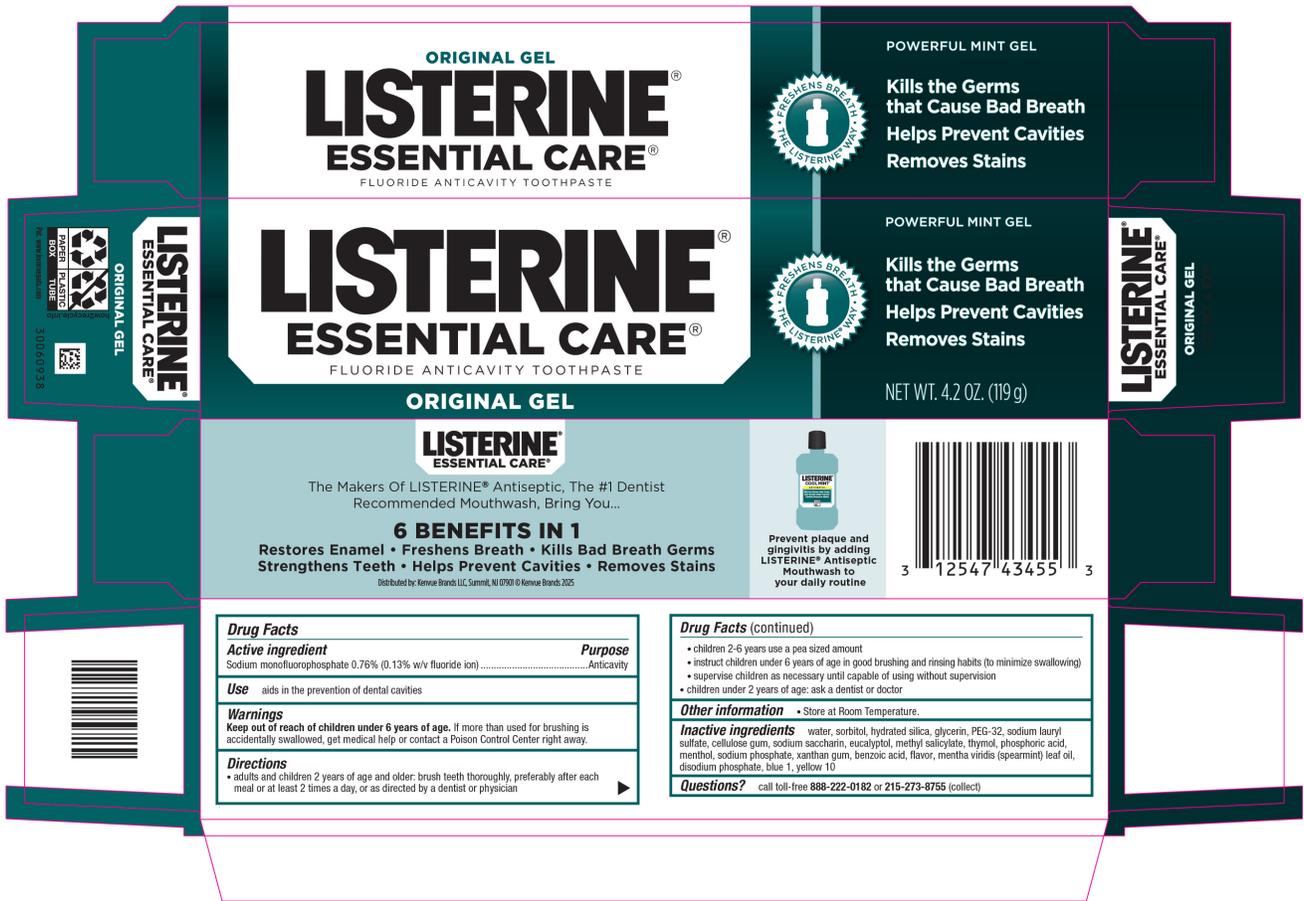
**Kills the Germs**

**that Cause Bad Breath**

**Helps Prevent Cavities**

**Removes Stains**

NET WT. 4.2 OZ. (119 g)



## LISTERINE ESSENTIAL CARE

sodium monofluorophosphate gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69968-0701
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.3 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

<b>POLYETHYLENE GLYCOL 1600</b> (UNII: 1212Z7S33A)
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)
<b>EUCALYPTOL</b> (UNII: RV6J6604TK)
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)
<b>THYMOL</b> (UNII: 3J50XA376E)
<b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)
<b>SPEARMINT OIL</b> (UNII: C3M81465G5)
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69968-0701-4	1 in 1 CARTON	03/03/2021	
1		119 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	03/03/2021	

**Labeler** - Kenvue Brands LLC (118772437)