

PERCARA KIDS BUBBLE GUM- sodium fluoride rinse
LEC Custom Products, Inc.

PerCara Bubblegum Fluoride Rinse

Drug Facts

Active Ingredients

Sodium fluoride 0.05% (Fluoride ion-0.0226%)

Purpose

Anticavity rinse

Uses

aids the prevention of dental cavities

Warning

Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 6 years of age and older, use once a day after brushing your teeth with a toothpaste
- Remove cap
- Use approximately one tablespoon and rinse vigorously 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
- supervise children as necessary until capable of using without supervision
- children under 6 years of age: consult a dentist or doctor

Inactive ingredients benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

Other information

- Store at room temperature

Distributed by: LEC Custom Products, Inc, Mississauga, ON L5S 1B8

MADE IN CANADA

PERCARA™

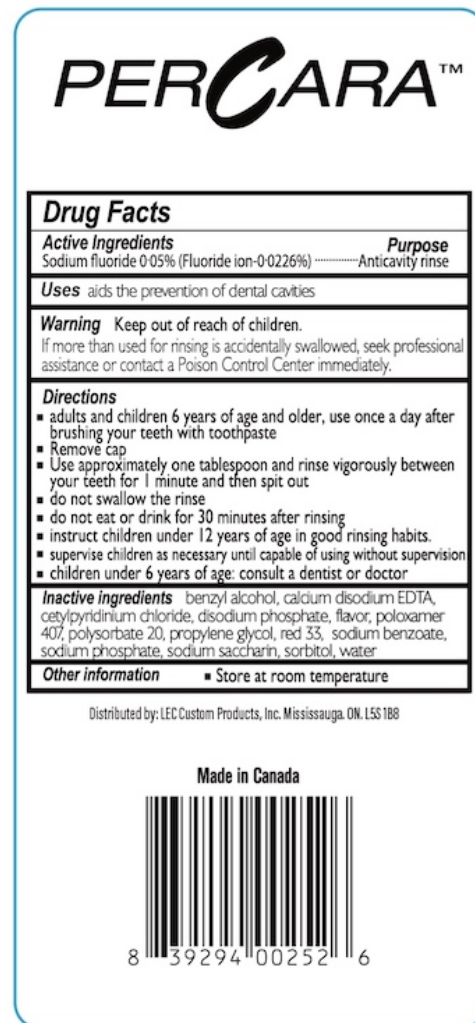
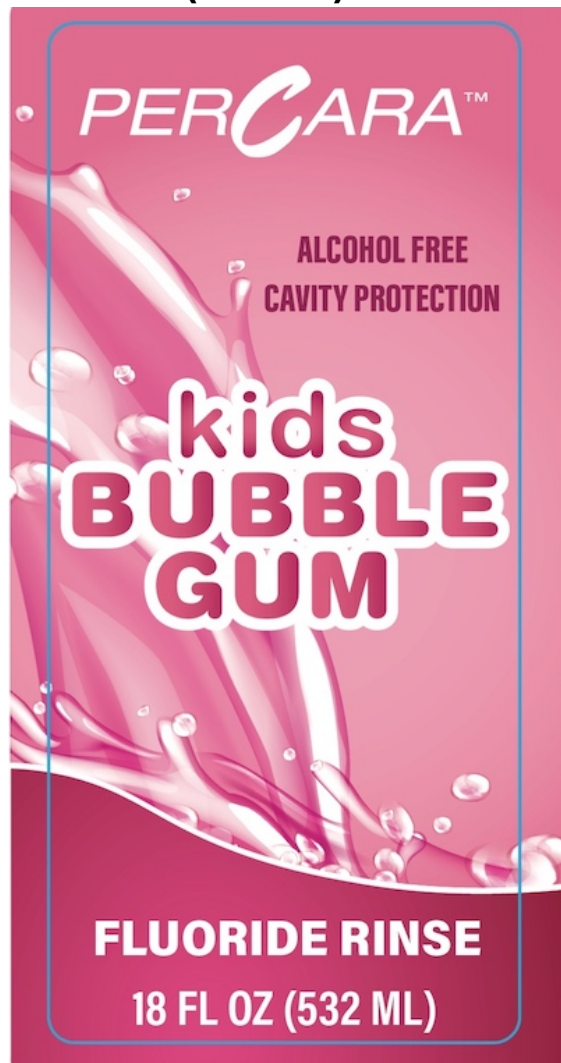
ALCOHOL FREE

CAVITY PROTECTION

kids BUBBLE GUM

FLUORIDE RINSE

18 FL OZ (532 ML)



PERCORA KIDS BUBBLE GUM

sodium fluoride rinse

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67933-0016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM ANHYDROUS (UNII: 8U5D034955)	

CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SODIUM PHOSPHATE DIBASIC DIHYDRATE (UNII: 9425516E2T)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67933-0016-1	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	03/23/2021	

Labeler - LEC Custom Products, Inc. (204065726)

Establishment

Name	Address	ID/FEI	Business Operations
LEC Custom Products, Inc		204064757	manufacture(67933-0016)

Revised: 1/2024

LEC Custom Products, Inc.