POP GEL PUMPIN STRAWBERRY- sodium fluoride paste, dentifrice LG H&H CO., LTD.

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.

POP Gel Pumpin' Strawberry Toothpaste 160g

Drug Facts

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Active Ingredient

SODIUM FLUORIDE 0.243% (0.13% w/v fluoride ion)

Purpose

Anticavity toopaste

Use

helps protect against cavities

Warnings

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Keep out of reach of children.

Keep out of reach of children under 6 years of age. Do not swallow. If you accidentally swallow more than used for brushing, seek professional assistance or contact a poison control center right away. If an allergic reaction develops, discontinue use immediately.

Directions

- adults and children 2 years of age and and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist.
- do not swallow.
- to minimize swallowing use a pea-sized amount in children under 6.
- supervise children's brushing until good habits are established.
- children under 2 years: ask a dentist.

Inactive Ingredients

GLYCERIN, WATER, HYDRATED SILICA, SODIUM LAURYL SULFATE, FLAVOR, XANTHAN GUM, TETRASODIUM PYROPHOSPHATE, POLOXAMER 407, SODIUM POLYACRYLATE, ZINC STEARATE, SODIUM SACCHARIN, SORBITAN OLEATE, TITANIUM DIOXIDE, SUCRALOSE, HYDROXYAPATITE, NIACINAMIDE, TOCOPHERYL ACETATE, XYLITOL

Questions?

1-866-993-4709

Principal Display Panel - 160 g Tube Carton POP

Playful. Original. Personal.

GEL TOOTHPASTE Electric Toothbrush Suitable 3X faster fluoride release* Repairs & protects enamel

Pumpin' Strawberry

NET WT. 5.64 OZ. (160 G)

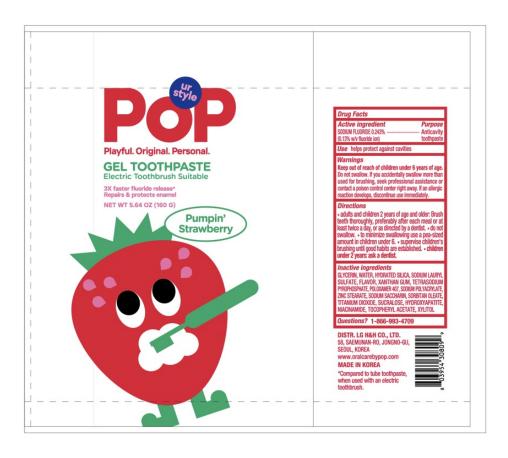
DISTR. LG H&H CO., LTD.

58, SAEMUNAN-RO, JONGNO-GU, SEOUL, KOREA www.oralcarebypop.com

MADE IN KOREA

*Compared to tube toothpaste, when used with an electric toothbrush.





POP GEL PUMPIN STRAWBERRY

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53208-581
Route of Administration	DENTAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 1.3 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)			
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)			
NIACINAMIDE (UNII: 25X5118RD4)			
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)			
WATER (UNII: 059QF0KO0R)			

ZINC STEARATE (UNII: H92E6QA4FV)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	MINT (Strawberry)	Imprint Code		
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53208-581- 60	1 in 1 CARTON	09/18/2023	
1		160 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 final	part355	09/18/2023	

Labeler - LG H&H CO., LTD. (688276187)

Establishment					
Name	Address	ID/FEI	Business Operations		
Tai Guk Pharma. Co., Ltd.		689060246	manufacture(53208-581)		

Revised: 9/2023 LG H&H CO., LTD.