COLGATE- sodium fluoride paste Buzz Export Services Pty., 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.

DENTAL KITS - COLGATE TOOTHPASTE

Drug Facts

Active Ingredient

Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)

Purpose

Anticavity

Use

helps protect against 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 twice a day, or as directed by a dentist or physician

children 2 to 6 years: use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)

children under 2 years: ask a dentist or physician

Inactive Ingredients

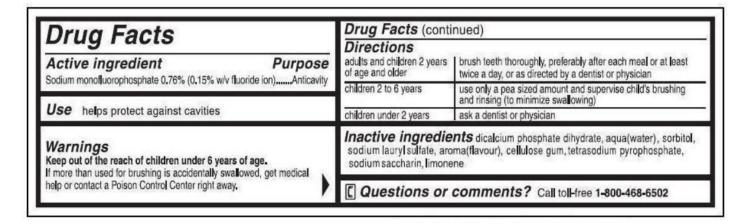
dicalcium phosphate dihydrate, water, glycerin, sodium lauryl sulfate, cellulose gum, flavor, tetrasodium pyrophosphate, sodium saccharin

Questions?

1-800-468-6502

Dist. by: COLGATE-PALMOLIVE COMPANY New York, NY 10022

DRUG FACTS PANEL INSERT



DENTAL KIT - COLGATE TOOTHPASTE 5g Labels

TUBE LABELING:



KIT PACKAGING:



DENTAL KIT - COLGATE TOOTHPASTE 10g

TUBE LABELING:



KIT PACKAGING:



sodium fluoride paste

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69491-060

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CODUM ELLOPIDE (LINII, 97VO1474M7) (FLLIOPIDE ION LINII, 999)/DLI4090)	ELLIODIDE ION	1 E ma in 1 a

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION

1.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69491-060- 45	1 in 1 BAG	12/03/2014		
1		5 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:69491-060- 94	1 in 1 CARTON	12/03/2014		
2		10 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	12/03/2014	

Labeler - Buzz Export Services Pty., Ltd. (747317902)

Establishment				
Name	Address	ID/FEI	Business Operations	
Zhejiang Baron Travel Product Co., Ltd.		554520509	repack(69491-060)	

Revised: 12/2021

Buzz Export Services Pty., Ltd.