

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

Drug Facts		Drug Facts (continued)	
Active ingredient Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion).....	Purpose Anticavity	Directions	
Use helps protect against cavities		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
Warnings Keep out of the 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.		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, aqua(water), sorbitol, sodium lauryl sulfate, aroma(flavour), cellulose gum, tetrasodium pyrophosphate, sodium saccharin, limonene	
		☐ Questions or comments? Call toll-free 1-800-468-6502	

DENTAL KIT - COLGATE TOOTHPASTE 5g Labels

TUBE LABELING:



KIT PACKAGING:



DENTAL KIT - COLGATE TOOTHPASTE 10g

TUBE LABELING:



KIT PACKAGING:



COLGATE

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
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	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)	

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
Hangzhou Zhuwen Inflight & Travel Products Co., Ltd.		421290194	repack(69491-060)

Revised: 3/2020

Buzz Export Services Pty., Ltd.