

COLGATE ANTICAVITY- sodium monofluorophosphate 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.

Colgate Anticavity 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 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.

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, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin

Questions or comments?

Call toll-free 1-800-468-6502

Package Labeling:69491-033-01

Drug Facts		Drug Facts (continued)	
Active ingredient Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)....Anticavity	Purpose	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
Use helps protect against cavities		children 2 to 6 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
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 under 2 years	ask a dentist or physician
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Read this full drug facts information before use

Manufactured by:
 COLGATE-PALMOLIVE (THAILAND) Limited, Chonburi 20000, Thailand. P1535077

Colgate[®]
Anticavity Toothpaste

Cavity Protection

NET WT 10 g (0.35 OZ)   OTHER

Drug Facts

Active Ingredient	Purpose
Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion).....	Anticavity

Use helps protect against cavities
See outer wrap for full Drug Facts before use.



COLGATE ANTICAVITY

sodium monofluorophosphate paste

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69491-033
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69491-033-01	10 g in 1 TUBE; Type 0: Not a Combination Product	10/15/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/15/2020	

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

Revised: 1/2023

Buzz Export Services Pty., Ltd.