

**5G COLGATE PLUS TOOTHBRUSH KIT- sodium monofluorophosphate
Colgate-Palmolive (Thailand) Limited - Branch**

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.

5g Colgate + Toothbrush Kit

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 to-free 1-800-468-6502

Package Labeling:

Manufactured by:

CP COLGATE-PALMOLIVE (THAILAND) Limited,
Chonburi 20000, Thailand.

P1535076

Colgate[®]
Anticavity Toothpaste

**Cavity
Protection**

NET WT 5 g (0.17 OZ)



OTHER

Drug Facts

Active Ingredient	Purpose
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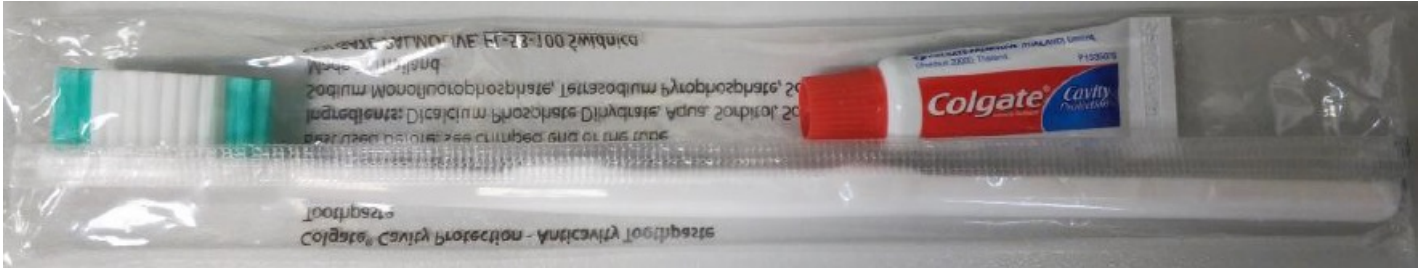
Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion).....	Anticavity
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Use helps protect against cavities

See outer wrap for full Drug Facts before use.

Drug Facts		Drug Facts (continued)	
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Read this full drug facts information before use



5G COLGATE PLUS TOOTHBRUSH KIT

sodium monofluorophosphate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42555-000
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42555-000-01	1 in 1 KIT	06/07/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	5 g

Part 1 of 1

COLGATE ANTICAVITY

sodium monofluorophosphate paste, dentifrice

Product Information

Item Code (Source)	NDC:42555-060
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
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42555-060-94	5 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	06/07/2018	

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OTC monograph final	part355	06/07/2018	

Labeler - Colgate-Palmolive (Thailand) Limited - Branch (672044552)**Establishment**

Name	Address	ID/FEI	Business Operations
Luoding Quality Amenities Supply Limited		528126807	repack(42555-000, 42555-060)

