10G COLGATE PLUS TOOTHBRUSH PLUS FLOSS 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.

10g Colgate + Toothbrush + Floss 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	brush teeth thoroughly, preferably after each meal or at least
years of age and older	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:



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

P1535077



NET WT 10 g (0.35 OZ)





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.

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Active ingredient

Purpose |

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

Drug Facts (continued)

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

Read this full drug facts information before use





10G COLGATE PLUS TOOTHBRUSH PLUS FLOSS KIT

sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42555-003

Packaging

l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:42555-003-01	1 in 1 KIT	06/07/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	10 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 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: K6790BS311)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	MINT	Imprint Code		
Contains				

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:42555-060- 45	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	06/07/2018		

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OTC monograph final	part355	06/07/2018	

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

Revised: 11/2022 Colgate-Palmolive (Thailand) Limited - Branch