5G 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.

5g 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:

Manufactured by:

CD COLGATE-PALMOLIVE (THAILAND) Limited,

Chonburi 20000, Thailand.

P1535076



NET WT 5 g (0.17 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.

Drug Facts	Drug Facts (continued)		
Active ingredient Purpose Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)Anticavity	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 children under 2 years	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing) ask 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,	Inactive ingredients dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, ilavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin		
get medical help or contact a Poison Control Center right away.	(Questions	or comments? Call toll-free 1-800-468-6502	

Read this full drug facts information before use





sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:42555-002

Packaging

l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:42555-002-01	1 in 1 KIT	06/07/2018	

Quantity of Parts

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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: K6790BS311)				
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				

Product Characteristics

Color	white	Score
Shape		Size
Flavor	MINT	Imprint Code
Contains		

Packaging				
4	tem 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)

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