

COLGATE ANTICAVITY KIT- sodium monofluorophosphate paste, dentifrice
Yangzhou Huayin Tourist Daily Necessities Co.,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.

Anticavity Toothpaste Kit

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**

PRINCIPAL DISPLAY PANEL - 5g Tube Label

Manufactured by:
COLGATE-PALMOLIVE (THAILAND) Limited,
 Chonburi 20000, Thailand. P1535076



NET WT 5 g (0.17 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.



Drug Facts		Drug Facts (continued)	
Active ingredient	Purpose	Directions	
Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)....	Anticavity	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		children under 2 years	ask a dentist or physician
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.		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 ZP3100161

COLGATE ANTICAVITY KIT			
sodium monofluorophosphate paste, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:7318 1-166
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
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
LIMONENE, (+/-)- (UNII: 9MC3B4447)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73181-166-88	1 in 1 PACKAGE	06/14/2019	
1		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	06/14/2019	

Labeler - Yangzhou Huayin Tourist Daily Necessities Co.,LTD (679949982)

Registrant - Yangzhou Huayin Tourist Daily Necessities Co.,LTD (679949982)

Establishment

Name	Address	ID/FEI	Business Operations
Colgate-Palmolive (Thailand) Limited - Branch		672044552	manufacture(73181-166)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Huayin Tourist Daily Necessities Co.,LTD		679949982	manufacture(73181-166)

Revised: 12/2020

Yangzhou Huayin Tourist Daily Necessities Co.,LTD