DELTA PREMIUM SELECT 2019 TUMI MORRISON AMENITY WITH COLGATE CAVITY PROTECTION- sodium monofluorophosphate 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.

DELTA PREMIUM SELECT 2019 - TUMI MORRISON - AMENITY KIT With Colgate Cavity Protection 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 apea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

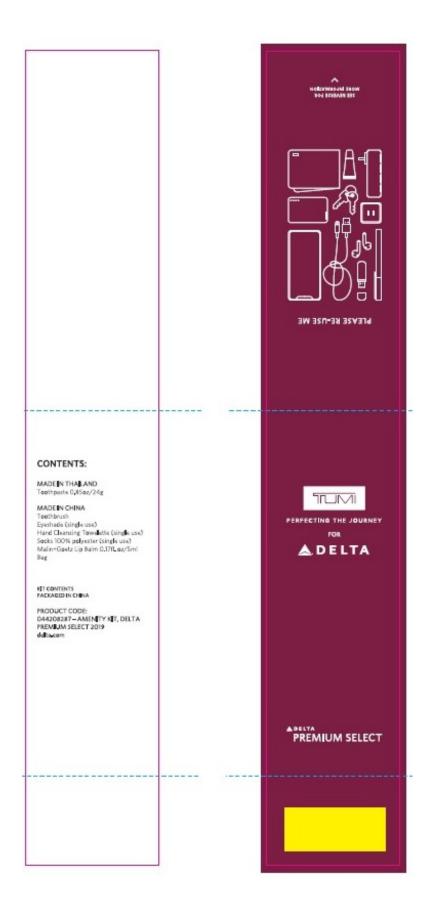
Inactive ingredients

dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin

Questions or comments?

1-800-492-7378

DELTA PREMIUM SELECT 2019 - TUMI MORRISON - AMENITY KIT With Colgate Cavity Protection Toothpaste (69491-205-00)



COLGATE ANTICAVITY 5g (42555-060-94)

Drug Facts

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 children 2 to 6 years brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician use only a pea sized amount and supervise child's brushing

and rinsing (to minimize swallowing)

children under 2 years | ask a

ars 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





DELTA PREMIUM SELECT 2019 TUMI MORRISON AMENITY WITH COLGATE CAVITY PROTECTION

sodium monofluorophosphate kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69491-205

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69491-205-00	1 in 1 KIT	04/01/2019		

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	

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

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

ı	Pa	Packaging			
4	#	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	04/01/2019	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	04/01/2019		

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

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