UNITED ASUTRA TC KIT COLGATE- sodium monofluorophosphate Procurall Solutions

UNITED Asutra TC Kit Colgate 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 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

Package Labeling:Kit

Front







Reference Image



Package Labeling:



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UNITED

Dental Kit



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.	Inactive ingressodium lauryl sulfate, flav	edients dicalcium phosphate dihydrate, water, sorbitol, lor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin
If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	(Questions	or comments? Call toll-free 1-800-468-6502
get medical help or contact a Poison Control Center right away. Read this full drug facts information before use,	(Questions	or comments? Call toll-free 1-800-468-6502

UNITED ASUTRA TC KIT COLGATE

sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83733-037

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ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1	NDC:83733-037-01	1 in 1 KIT	08/07/2023	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1 1 TUB	BE	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	1.5 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)	
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
ı	Contains		

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
ı		NDC:42555-060- 94	5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing Category Citation Date Date				
OTC Monograph Drug	M021	08/07/2023		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	08/07/2023	

Labeler - Procurall Solutions (119083552)

Revised: 8/2023 Procurall Solutions