DELTA TRAVEL KIT COMFORT PLUS- sodium monofluorophosphate Buzz Export Services Pty Ltd (Buzz Products)

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 Travel Kit Comfort plus

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?

Package Labeling:69491-039-01













Package Labeling:42555-060-94

Drug Facts (continued) Drug Facts Directions Purpose Active ingredient adults and children 2 brush teeth thoroughly, preferably after each meal or at years of age and older least twice a day, or as directed by a dentist or physician Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion) Anticavity use only a pea sized amount and supervise child's brushing children 2 to 6 years and rinsing (to minimize swallowing) USE helps protect against cavities children under 2 years ask a dentist or physician Inactive ingredients dicalcium phosphate dihydrate, water, sorbitol, Warnings sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium Keep out of the reach of children under 6 years of age. 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



DELTA TRAVEL KIT COMFORT PLUS

sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69491-039

Packaging

Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:69491-039-01 1 in 1 KIT 05/01/2022

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

Active Ingredient/Active Moiety Ingredient Name Basis of Strength Sodium Monofluorophosphate (UNII: C810JCZ56Q) (FLUORIDE ION - FLUORIDE ION 1 g 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 (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- 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	05/01/2022		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part355	05/01/2022	

Labeler - Buzz Export Services Pty Ltd (Buzz Products) (747317902)

Revised: 1/2023 Buzz Export Services Pty Ltd (Buzz Products)