MURCHISON HUME DENTAL KIT- 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.

Murchison-Hume Dental Kit Toothbrush and Toothpaste

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)

Purpose

Anticavity

Indication

Aids in the prevention of dental 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 brushing and rinsing (Do not swallow)
children under 2 years	ask a dentist or physician

Non medicinal ingredients

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

Questions or comments?

Package Labeling:Kit



Package Labeling:69491-033-01

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	use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
OSE helps protect against cavilles	children under 2 years	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, flavor, 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

Manufactured by:

COLGATE-PALMOLIVE (THAILAND) Limited, Chonburi 20000, Thailand.

P1535077



NET WT 10 g (0.35 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.



MURCHISON HUME DENTAL KIT

sodium monofluorophosphate kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69491-034

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:69491-034-01	1 in 1 KIT	10/15/2020		

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 TUBE	10 g		

Part 1 of 1

COLGATE ANTICAVITY

sodium monofluorophosphate paste

Product Information		
Item Code (Source)	NDC:69491-033	
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
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)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69491-033- 01	10 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	10/15/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/15/2020	

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

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