

**UA MAIN CABIN HAWAII PREMIUM 2020 W COLGATE- sodium monofluorophosphate  
Buzz Products (HK) Co. Limited**

*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.*

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**UA Main Cabin Hawaii Premium Kit 2020 w 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***

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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 (to minimize swallowing)
children under 2 years	ask a dentist or physician

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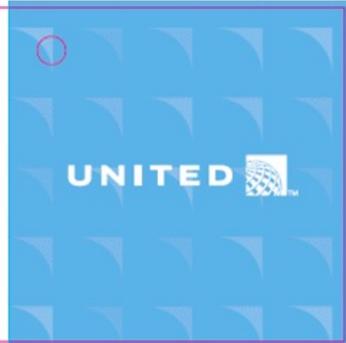
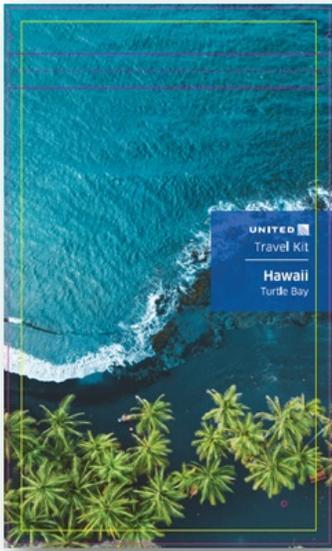
***Inactive ingredients***

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

***Questions or comments?***

Call toll-free 1-800-492-7378

**Package Labeling: (69491-235-00)**



Package Labeling: (69491-060-94)

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

P1535076

**Colgate**<sup>®</sup> *Cavity Protection*  
 Anticavity Toothpaste

NET WT 5 g (0.17 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.

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b>	<b>Purpose</b>	<b>Directions</b>	
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 a least twice a day, or as directed by a dentist or physician
<b>Use</b> helps protect against cavities		children 2 to 6 years	use only a pea sized amount and supervise child brushing and rinsing (to minimize swallowing)
<b>Warnings</b> 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.		children under 2 years	ask a dentist or physician
		<b>Inactive ingredients</b> dicalcium phosphate dihydrate, water, sorbitol, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, sodium saccharin	
		<b>Questions or comments?</b> Call toll-free 1-800-468-6502	

Read this full drug facts information before use.



<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient</b>	<b>Purpose</b>	<b>Directions</b>	
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## UA MAIN CABIN HAWAII PREMIUM 2020 W COLGATE

sodium monofluorophosphate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70402-235
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70402-235-00	1 in 1 KIT	03/13/2020	

### 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

<b>Item Code (Source)</b>	NDC:42555-060
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<b>Route of Administration</b>	DENTAL
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**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	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	03/13/2020	

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OTC monograph final	part355	03/13/2020	

**Labeler** - Buzz Products (HK) Co. Limited (663516515)