

**DELTA COMFORT PLUS 2019 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.*

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**DELTA COMFORT PLUS 2019 - 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***

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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's brushing and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

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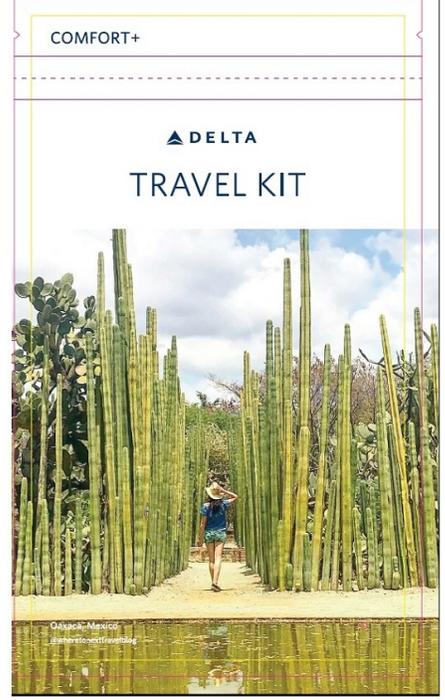
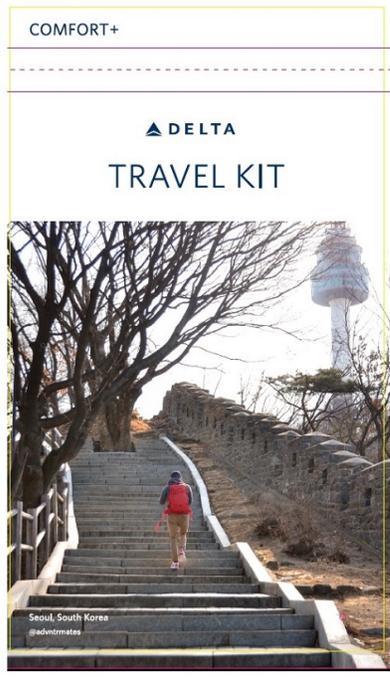
***Inactive ingredients***

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

**Questions or comments?**

1-800-492-7378

**DELTA COMFORT PLUS 2019 - AMENITY KIT With Colgate Cavity Protection Toothpaste (69491-210-00)**



**COLGATE ANTICAVITY 5g (42555-060-94)**

## Drug Facts

### Active ingredient

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

### Purpose

**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)

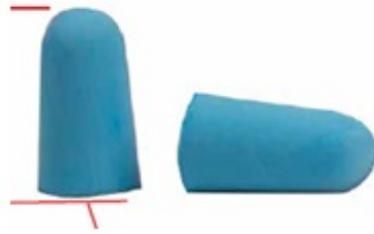
### Directions

adults and children 2 years of age and older	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





## DELTA COMFORT PLUS 2019 AMENITY WITH COLGATE CAVITY PROTECTION

sodium monofluorophosphate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69491-210
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69491-210-00	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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	7.6 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<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	04/01/2019	

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OTC monograph final	part355	04/01/2019	

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