

**COLGATE- sodium fluoride paste**  
**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.*

-----  
**DENTAL KITS - 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 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, glycerin, sodium lauryl sulfate, cellulose gum, flavor, tetrasodium pyrophosphate, sodium saccharin

## Questions?

1-800-468-6502

Dist. by: COLGATE-PALMOLIVE COMPANY New York, NY 10022

## DRUG FACTS PANEL INSERT

<b>Drug Facts</b>		<b>Drug Facts</b> (continued)	
<b>Active ingredient</b> Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion).....Anticavity	<b>Purpose</b> Anticavity	<b>Directions</b> 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
<b>Use</b> 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)
<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, aqua(water), sorbitol, sodium lauryl sulfate, aroma(flavour), cellulose gum, tetrasodium pyrophosphate, sodium saccharin, limonene
		<b>Questions or comments?</b> Call toll-free 1-800-468-6502	

## DENTAL KIT - COLGATE TOOTHPASTE 5g Labels

TUBE LABELING:



KIT PACKAGING:



**DENTAL KIT - COLGATE TOOTHPASTE 10g**

TUBE LABELING:



KIT PACKAGING:



sodium fluoride paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69491-060
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.5 mg in 1 g

### Inactive Ingredients

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

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:69491-060-45	1 in 1 BAG	12/03/2014	
1		5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69491-060-94	1 in 1 CARTON	12/03/2014	
2		10 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	12/03/2014	

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

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Zhejiang Baron Travel Product Co., Ltd.		554520509	repack(69491-060)

