# COLGATE JUNIOR BUBBLEFRUIT- sodium fluoride gel, dentifrice Colgate-Palmolive Canada

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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Colgate<sup>®</sup>
JUNiOR
Bubble Fruit<sup>®</sup>

**Drug Facts** 

### **Active ingredients**

Sodium fluoride 0.24% (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	brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician	
	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**

sorbitol, water, hydrated silica, PEG-12, cellulose gum, flavor, sodium lauryl sulfate, sodium saccharin, mica, titanium dioxide, FD&C blue no. 1

Questions?

1-800-468-6502

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

# PRINCIPAL DISPLAY PANEL - 70 g Carton

Colgate<sup>®</sup> Anticavity Fluoride Toothpaste

<u>ADA</u>

**Accepted** 

American

Dental

Association  ${\mathbb R}$ 

NET WT 2.5 OZ (70 g)

**JUNIOR** 

**Bubble Fruit**®

Flavor





Purpose

Active ingredients
Sodium fluoride 0.24% (0.15% w/v fluoride ion) ...

its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed." Dist. by:

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.



COLGATE-PALMOLIVE COMPANY New York, NY 10022

"The ADA Council on Scientific Affairs' Acceptance of

Colgate for Kids toothpaste is based on

### Drug Facts (continued)

#### Directions

adults and children 2 years of age and

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)

ask a dentist or physician

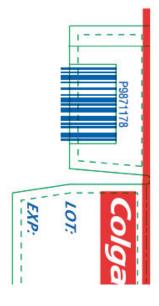
children under 2 years

#### Drug Facts (continued)

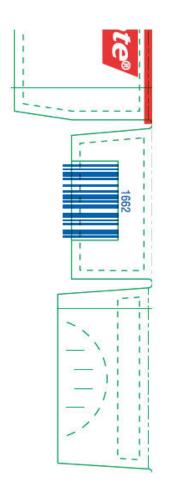
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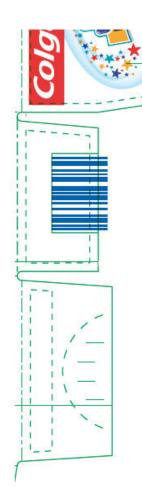
Questions? 1-800-468-6502











## COLGATE JUNIOR BUBBLEFRUIT

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51442-327
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	Sodium Fluoride	2.4 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
sorbitol (UNII: 506T60A25R)		
water (UNII: 059QF0KO0R)		
hydrated silica (UNII: Y6O7T4G8P9)		
Polyethylene Glycol 600 (UNII: NL4J9F21N9)		
Carboxymethylcellulose Sodium (UNII: K679OBS311)		
sodium lauryl sulfate (UNII: 368GB5141J)		
Saccharin Sodium (UNII: SB8ZUX40TY)		
mica (UNII: V8A1AW0880)		

titanium dioxide (UNII: 15FIX9 V2JP)	
FD&C Blue no. 1 (UNII: H3R47K3TBD)	

Product Characteristics			
Color	BLUE (Pearlescent)	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:51442-327-58	70 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/25/2011	

# Labeler - Colgate-Palmolive Canada (259157246)

Revised: 7/2011 Colgate-Palmolive Canada