COLGATE JUNIOR BUBBLE FRUIT- sodium fluoride gel, dentifrice Colgate-Palmolive Company

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.

Colgate® JUNIOR BUBBLE FRUIT® Fluoride Toothpaste Drug Facts

Active ingredient

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 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	use only a pea sized amount and supervise child's brushing
years	and rinsing (to minimize swallowing)
children under 2 years	ask a dentist or physician

Inactive ingredients

sorbitol, water, hydrated silica, PEG-12, cellulose gum, sodium lauryl sulfate, flavor, sodium saccharin, D&C yellow no. 10, FD&C blue no. 1

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE

COMPANY, New York, NY 10022

PRINCIPAL DISPLAY PANEL - 24 g Tube Carton

Colgate® Anticavity Fluoride Toothpaste

Kids

Cavity

Protection

Bubble Fruit® Flavor

Fights

Cavities

Clinically

Proven

Enamel

Safe

ADA

Accepted

American

Dental

Association ®

NET WT 0.85 OZ (24 g)



COLGATE JUNIOR BUBBLE FRUIT

sodium fluoride gel, dentifrice

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-926

Route of Administration DENTAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	476 mg in 1 g
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics				
Color	GREEN	Score		
Shape		Size		
Flavor	FRUIT	Imprint Code		
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:35000-926- 59	1 in 1 CARTON	11/11/2016		
1		76 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:35000-926- 20	1 in 1 CARTON	11/11/2016		
2		24 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:35000-926- 46	1 in 1 CARTON	11/11/2016		
3		130 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	11/11/2016		

Colgate-Palmolive Company

Labeler - Colgate-Palmolive Company (001344381)