# COLGATE KIDS LLAMA MILD BUBBLE FRUIT FLAVOR- 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.

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Colgate<sup>®</sup> Kids Llama Mild Bubble Fruit<sup>®</sup> Flavor

**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 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**

Sorbitol, Water, Hydrated Silica, PEG-12, Cellulose Gum, Sodium Lauryl Sulfate, Flavor, Sodium Saccharin, Blue 1, Yellow 10.

Questions?

1-800-468-6502

Dist. by:

**COLGATE-PALMOLIVE** CO.

## PRINCIPAL DISPLAY PANEL - 130 g Tube Label

Colgate®

Anticavity Fluoride Toothpaste

Clinically

Proven

**Cavity Protection** 

 $Mild\,BUBBLE\,FRUIT^{\circledR}$ 

ADA

Accepted

American

Dental

Association ®

NET WT 4.6 OZ (130g)



#### COLGATE KIDS LLAMA MILD BUBBLE FRUIT FLAVOR

sodium fluoride gel, dentifrice

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:35000-986

**Route of Administration** DENTAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM ELLIORIDE (UNII: 87YO 1474W7) (ELLIORIDE ION - UNII: 080 VPI 1408O)	FLUORIDE ION	11 mg in 1 g

#### **Inactive Ingredients**

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Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)	476 mg in 1 g	
WATER (UNII: 059QF0KO0R)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)		
CARBO XYMETHYLCELLULO SE SO DIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
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**

l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
l	1 NDC:35000-986-46	130 g in 1 TUBE; Type 0: Not a Combination Product	05/05/2020	

## **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	05/05/2020	

# Labeler - Colgate-Palmolive Company (001344381)

Revised: 4/2020

Colgate-Palmolive Company