# COLGATE 2IN1 WHITENING STAIN LIFTERS- 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® 2IN1 TOOTHPASTE AND MOUTHWASH WHITENING STAIN LIFTERS

**Drug Facts** 

## **Active ingredient**

Sodium fluoride 0.24% (0.14% w/v fluoride ion)

## Purpose

Anticavity

#### Use

aids in the prevention of 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**

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**

water, sorbitol, hydrated silica, glycerin, sodium lauryl sulfate, flavor, tetrasodium pyrophosphate, sodium saccharin, cocamidopropyl betaine, cellulose gum, xanthan gum, titanium dioxide

#### Questions?

Call toll-free 1-800-468-6502

Dist.

by:

CP COLGATE-PALMOLIVE COMPANY New York, NY 10022

## PRINCIPAL DISPLAY PANEL - 130 g Bottle Label

2 in 1

Toothpaste & Mouthwash

 $Colgate^{ ext{ extit{R}}}$ 

Fluoride Toothpaste

Cleans Teeth & Freshens Breath

Whitening with Stain Lifters

NET WT 4.6 OZ (130 g) LIQUID GEL



#### COLGATE 2IN1 WHITENING STAIN LIFTERS

sodium fluoride gel, dentifrice

## **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-907
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8 ZYQ 1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients		
Ingredient Name	Strength	
SORBITOL (UNII: 506T60A25R)	331.2 mg in 1 g	
WATER (UNII: 059QF0KO0R)		
GLYCERIN (UNII: PDC6A3C0OX)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
COCAMIDO PRO PYL BETAINE (UNII: 50CF3011KX)		
SODIUM PYROPHO SPHATE (UNII: O352864B8Z)		
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679 OBS 311)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

l	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
l	1 NDC:35000-907-81	130 g in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part355	07/26/2011	

## **Labeler** - Colgate-Palmolive Company (001344381)