# ULTRABRITE- sodium fluoride paste, 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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**Ultrabrite**®

**Drug Facts** 

#### **Active ingredient**

Sodium Fluoride 0.24% (0.15% w/v f uoride 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**

vears 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
	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, Sodium Lauryl Sulfate, Flavor, PEG-12, Tetrasodium Pyrophosphate, Cocamidopropyl Betaine, Cellulose Gum, Sodium Saccharin, Xanthan Gum, Titanium Dioxide.

#### Questions?

1-800-468-6502

Dist. by:

**COLGATE-PALMOLIVE** COMPANY

New York, NY 10022 U.S.A.

#### PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

# **CLEAN MINT**

Ultrabrite® ANTICAVITY FLUORIDE TOOTHPASTE

WHITENS TEETH Advanced Whitening All in One Toothpaste

NET WT 6.0 OZ (170 g)











# **ULTRABRITE**

sodium fluoride paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-129
Route of Administration	DENTAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1.1 mg in 1 g	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
SORBITOL (UNII: 506T60A25R)			
HYDRATED SILICA (UNII: Y6O7T4G8P9)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)			
SODIUM PYROPHO SPHATE (UNII: O352864B8Z)			
COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX)			
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)			
SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)			
XANTHAN GUM (UNII: TTV12P4NEE)			
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)			

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>
	1 NDC:35000-129-60	:35000-129-60 1 in 1 CARTON		

170 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 FINA	part355	08/01/2019	

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Colgate-Palmolive		785047999	MANUFACTURE(35000-129)	

Revised: 12/2019 Colgate-Palmolive Company