

COLGATE ESSENTIALS- sodium monofluorophosphate 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.

Colgate® Essentials™ Toothpaste

Drug Facts

Active ingredient

Sodium monofluorophosphate 0.76% (0.10% 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

water, hydrated silica, sorbitol, calcium pyrophosphate, glycerin, PEG-12, pentasodium triphosphate, tetrapotassium pyrophosphate, flavor, sodium lauryl sulfate, cellulose gum, sodium saccharin, charcoal powder, xanthan gum, cocamidopropyl betaine, blue 1, red 40, yellow 5

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 130 g Tube Carton

NEW

Colgate®

Anticavity Fluoride Toothpaste

ESSENTIALS™

WITH CHARCOAL

Daily toothpaste removes stains and impurities
for whiter teeth and fresher breath

NET WT 4.6 OZ (130g)

ENAMEL SAFE

FRESH MINT

Colgate[®]

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DIST. BY:
COLGATE-PALMOLIVE COMPANY
New York, NY 10022 U.S.A.
www.colgate.com
Made in Mexico

GLUTEN FREE

smartlabel[™]
app enabled
scan for more information



Colgate[®]

ESSENTIALS[™]

WITH CHARCOAL

Enamel Safe fluoride formula

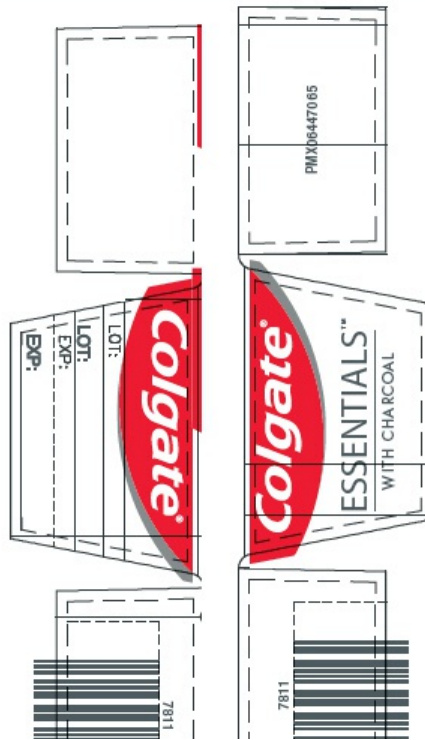


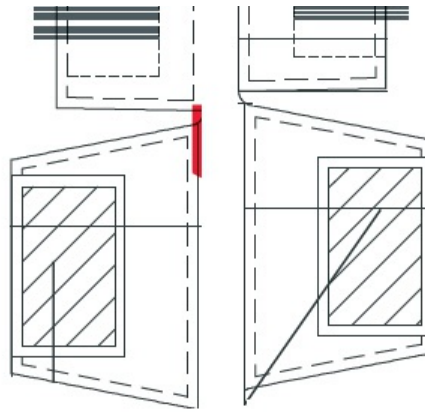
Cooling mint flavor freshens breath

Daily toothpaste contains micropolishers to safely remove stains



Turning off your water while brushing your teeth can save up to 4 gallons of water each time you brush!





COLGATE ESSENTIALS

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:35000-974
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.0 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	181.01 mg in 1 g
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SORBITOL (UNII: 506T60A25R)	
CALCIUM PYROPHOSPHATE (UNII: X69NU20D19)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
SODIUM TRIPOLYPHOSPHATE ANHYDROUS (UNII: 9SW4PFD2FZ)	
POTASSIUM PYROPHOSPHATE (UNII: B9W4019H5G)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
ACTIVATED CHARCOAL (UNII: 2P3VWU3H10)	
XANTHAN GUM (UNII: TTV12P4NEE)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	GRAY	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35000-974-61	1 in 1 CARTON	04/09/2018	
1		172 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:35000-974-46	1 in 1 CARTON	10/12/2018	
2		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 not final	part356	04/09/2018	

Labeler - Colgate-Palmolive Company (001344381)

Revised: 12/2019

Colgate-Palmolive Company