

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

Colgate®

Anticavity Fluoride Toothpaste

REVITALIZING

WHITE

whitening toothpaste

with

activated charcoal

NET WT 4.6 OZ (130g)

FRESH MINT

Colgate®

Anticavity Fluoride Toothpaste

NET WT 4.6 OZ (130 g)

FRESH MINT

REVITALIZING WHITE

whitening toothpaste
with
activated charcoal

Colgate®

Anticavity Fluoride Toothpaste

NET WT 4.6 OZ (130 g)

FRESH MINT

REVITALIZING WHITE

whitening toothpaste
with
activated charcoal

Drug Facts

Active ingredient

Sodium Monofluorophosphate 0.76% (0.10% w/v fluoride ion).....Anticavity

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.

Drug Facts (continued)

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, Calcium Pyrophosphate, Glycerin, PEG-12, Pentasodium Triphosphate, Tetrapotassium Pyrophosphate, Flavor, Sodium Lauryl Sulfate, Cellulose Gum, Xanthan Gum, Charcoal Powder, Sodium Saccharin, Cocamidopropyl Betaine, Blue 1, Red 40, Yellow 5.

Questions? 1-800-468-6502



SAVE WATER
turn off the tap while brushing

Dist. by:
COLGATE-PALMOLIVE CO.
New York, NY 10022 U.S.A.
www.colgate.com
Made in Mexico



app enabled
scan for more information



Colgate®

HELPS KEEP YOUR TEETH WHITE AND BRIGHT

REVITALIZING WHITE

whitening toothpaste
with
activated charcoal



MICROPOLISHERS TO
SAFELY REMOVE STAINS



ENAMEL-SAFE FLUORIDE
TOOTH PASTE WITH
CLINICALLY PROVEN
CAVITY PROTECTION



COOLING MINT FLAVOR
TO KEEP YOU FRESH



Vegan



Gluten Free



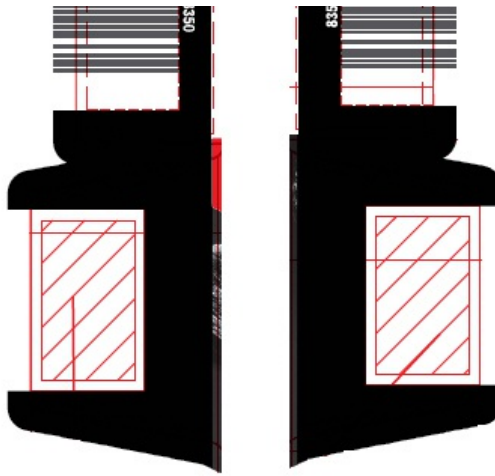
Responsibly
Made™



Sugar Free

To learn more, visit
www.colgate.com/responsibly-made





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: 5OCF3011KX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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: 4/2020

Colgate-Palmolive Company