

COLGATE MAXCLEAN WITH WHITENING SMARTFOAM- sodium fluoride paste, dentifrice

Colgate-Palmolive

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® MaxClean™ with Whitening Smartfoam®

Drug Facts

Active ingredient

Sodium Fluoride 0.24% (0.14% 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, Sorbitol, Hydrated Silica, PEG-12, Poloxamer 407, Sodium Lauryl Sulfate, Flavor, Xanthan Gum, Cocamidopropyl Betaine, Tetrasodium Pyrophosphate Sodium Saccharin, Mica, Hydroxypropyl Methylcellulose, Blue 1, Titanium Dioxide.

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE CO.

New York, NY 10022 U.S.A.

PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

Colgate®

Anticavity Fluoride Toothpaste

NET WT 6.0 OZ (170 g)

EFFERVESCENT MINT

MaxClean™

with WHITENING

SmartFoam®

30% MORE FOAM*

CLEANS TOUGH TO REACH SPACES

Colgate[®]
Anticavity Fluoride Toothpaste

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Colgate[®] **MaxClean**
with WHITENING
SmartFoam[®]

Cleans Tough to Reach Spaces

Bursts into foam as you brush to penetrate between teeth and around gums - helping to remove bad breath germs, even in tough to reach spaces.

- ✓ Fights Cavities
- ✓ Whitens Teeth
- ✓ Freshens Breath

vs. a leading fluoride toothpaste

Drug Facts

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Use helps protect against cavities

Warnings

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Drug Facts (continued)

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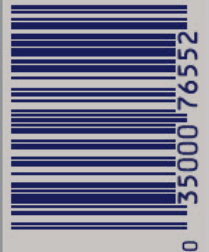


SAVE WATER

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

www.colgate.com/maxclean
DIXIE
COLGATE-PALMOLIVE CO.
New York, NY 10022 U.S.A.

GLUTEN FREE



0 35000 76552 9



P9935805



COLGATE MAXCLEAN WITH WHITENING SMARTFOAM

sodium fluoride paste, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-028 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | FLUORIDE ION | 1.1 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0K00R) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9) | |
| POLOXAMER 407 (UNII: TUF2IVW3M2) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)

SODIUM PYROPHOSPHATE (UNII: O352864B8Z)

SACCHARIN SODIUM (UNII: SB8ZUX40TY)

MICA (UNII: V8A1AW0880)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

FD&C BLUE NO. 1 (UNII: HBR47K3TBD)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

| | | | |
|-----------------|------|---------------------|--|
| Color | BLUE | Score | |
| Shape | | Size | |
| Flavor | MINT | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:35000-028-60 | 1 in 1 CARTON | 10/24/2019 | |
| 1 | | 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 FINAL | part355 | 10/24/2019 | |

Labeler - Colgate-Palmolive (001344381)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| Colgate-Palmolive | | 785047999 | MANUFACTURE(35000-028) |

Revised: 12/2019

Colgate-Palmolive