COLGATE MAXFRESH WITH MINI BREATH COOL MINT- 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.

Colgate® MaxFresh® with Mini Breath Cool Mint

Drug Facts

Active ingredient

Sodium fluoride 0.24% (0.15% 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

sorbitol, water, hydrated silica, PEG-12, sodium lauryl sulfate, flavor, cellulose gum, tetrasodium pyrophosphate, cocamidopropyl betaine, sodium saccharin, methylcellulose, FD&C blue no. 1

Questions?

1-800-468-6502

Dist. by:

COLGATE-PALMOLIVE COMPANY

New York, NY 10022

PRINCIPAL DISPLAY PANEL - 170 g Tube Carton

Colgate[®] Anticavity Fluoride Toothpaste

 $MaxFresh^{\circledR}$

with WHITENING

BREATH STRIPS

FRESHNESS THAT LASTS FOR HOURS!

NET WT 6.0 OZ (170 g)

COOL MINT



Drug Facts

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Use helps protect against cavities

Warnings

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Drug Facts (continued)

Directions

children 2 to 6 years

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Questions? 1-800-468-6502

SAVE WATER

? smartlabel™



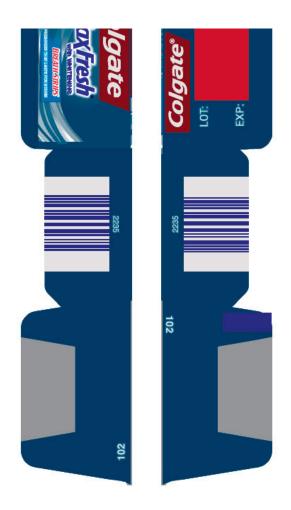
GLUTEN FREE

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COLGATE MAXFRESH WITH MINI BREATH COOL MINT

sodium fluoride paste, dentifrice

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:35000-014 |
| 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 | | |
| SORBITOL (UNII: 506T60A25R) | | | |
| WATER (UNII: 059QF0KO0R) | | | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | | | |
| POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9) | | | |
| SO DIUM LAURYL SULFATE (UNII: 368 GB5141J) | | | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | | | |
| SODIUM PYROPHO SPHATE (UNII: O352864B8Z) | | | |
| COCAMIDO PRO PYL BETAINE (UNII: 50 CF3 O 11 KX) | | | |

SACCHARIN SO DIUM (UNII: SB8 ZUX40 TY)

METHYLCELLULOSE (100 MPA.S) (UNII: 4GFU244C4J)

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

| 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:35000-014-99 | 1 in 1 CARTON | 09/23/2013 | |
| 1 | | 53 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:35000-014-60 | 1 in 1 CARTON | 09/23/2013 | |
| 2 | | 170 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:35000-014-34 | 2 in 1 CARTON | 09/23/2013 | |
| 3 | | 170 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:35000-014-78 | 1 in 1 CARTON | 09/23/2013 | |
| 4 | | 221 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 5 | NDC:35000-014-01 | 1 in 1 CARTON | 09/23/2013 | |
| 5 | | 28 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 6 | NDC:35000-014-79 | 1 in 1 CARTON | 09/23/2013 | |
| 6 | | 70 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 7 | NDC:35000-014-70 | 1 in 1 CARTON | 11/30/2016 | |
| 7 | | 215 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 | 09/23/2013 | |
| | | | |

Labeler - Colgate-Palmolive Company (001344381)

| Establishment | | | | |
|-------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Colgate-Palmolive | | 785047999 | MANUFACTURE(35000-014) | |

Revised: 12/2019 Colgate-Palmolive Company