# COLGATE PROCLINICAL - SPARKLING MINT- sodium fluoride paste, dentifrice Colgate-Palmolive Canada

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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Colgate® FLUORIDE TOOTHPASTE

## **Drug Facts**

# **Active ingredients**

Sodium fluoride 0.24% (0.15% w/v fluoride ion)

# **Purpose**

Anticavity

### Uses

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<br>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, glycerin, PEG-12, pentasodium triphosphate, tetrasodium pyrophosphate, sodium lauryl sulfate, flavor, cellulose gum, polyethylene, cocoamidopropyl betaine, sodium hydroxide, sodium saccharin, xanthan gum, titanium dioxide, FD&C blue no. 1

#### Questions or comments?

Call toll free 1-800-468-6502

Dist. by:

#### **COLGATE-PALMOLIVE** COMPANY

New York, NY 10022 Made in Canada www.colgateproclinical.com

## PRINCIPAL DISPLAY PANEL - 113 g Carton

Colgate<sup>®</sup>

**Anticavity Fluoride Whitening Toothpaste** 

Paste

**PRO** 

**CLINICAL**<sup>TM</sup>

white

#### WHITER TEETH IN JUST 1 TUBE

NET WT 4.0 OZ (113 g)

Clinically Proven WHITENING TECHNOLOGY.



# **COLGATE PROCLINICAL - SPARKLING MINT**

sodium fluoride paste, dentifrice

| Product | <b>Information</b> |
|---------|--------------------|
| Product | IIIIVI IIId UVII   |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:51442-543

Route of Administration DENTAL

## Active Ingredient/Active Moiety

|                 | retive ingredient retive with the                                   |                   |               |  |
|-----------------|---|-------------------|---------------|--|
| Ingredient Name |   | Basis of Strength | Strength      |  |
|                 | Sodium Fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) | Sodium Fluoride   | 2.4 mg in 1 g |  |

# Inactive Ingredients

| mactive ingredients                              |          |  |
|--|----------|--|
| Ingredient Name                                  | Strength |  |
| Water (UNII: 059QF0KO0R)                         |          |  |
| Hydrated Silica (UNII: Y6O7T4G8P9)               |          |  |
| Sorbitol (UNII: 506T60A25R)                      |          |  |
| Glycerin (UNII: PDC6A3C0OX)                      |          |  |
| Polyethylene Glycol 600 (UNII: NL4J9F21N9)       |          |  |
| Sodium Tripolyphosphate (UNII: 5HK03SA80J)       |          |  |
| Sodium Pyrophosphate (UNII: O352864B8Z)          |          |  |
| Sodium Lauryl Sulfate (UNII: 368GB5141J)         |          |  |
| Carboxymethylcellulose Sodium (UNII: K679OBS311) |          |  |
| Cocamidopropyl Betaine (UNII: 5OCF3O11KX)        |          |  |
| Sodium Hydroxide (UNII: 55X04QC32I)              |          |  |
| Saccharin Sodium (UNII: SB8ZUX40TY)              |          |  |
| Xanthan Gum (UNII: TTV12P4NEE)                   |          |  |
| Titanium Dioxide (UNII: 15FIX9V2JP)              |          |  |
| FD&C Blue No. 1 (UNII: H3R47K3TBD)               |          |  |

# **Product Characteristics**

| Color    | WHITE (Blue Speckles) | Score        |
|----------|-----------------------|--------------|
| Shape    |                       | Size         |
| Flavor   | MINT                  | Imprint Code |
| Contains |                       |              |

| Packaging          |                     |                      |                    |
|--------------------|---------------------|----------------------|--------------------|
| # Item Code        | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:51442-543-69 | 1 in 1 CARTON       |                      |                    |
| 1                  | 113 g in 1 TUBE     |                      |                    |

| Marketing Information |  |                      |                    |
|-----------------------|--|----------------------|--------------------|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC MONOGRAPH FINAL   | part355                                  | 11/10/2010           |                    |
|                       |  |                      |                    |

# Labeler - Colgate-Palmolive Canada (259157246)

Revised: 12/2010 Colgate-Palmolive Canada