

**COLGATE GREAT REGULAR FLAVOR - 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® Great Regular Flavor Fluoride Toothpaste**

**Drug Facts**

**Active ingredient**

Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

helps protect against cavities

**Warnings**

**Keep out of the 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**

dicalcium phosphate dihydrate, water, glycerin, sodium lauryl sulfate, cellulose gum, flavor, tetrasodium pyrophosphate, sodium saccharin

**Questions or comments?**

Call toll-free **1-800-468-6502**

*Dist. by:*

**COLGATE-PALMOLIVE COMPANY**

*New York, NY 10022*

**PRINCIPAL DISPLAY PANEL - 113 g Tube Carton**

**Colgate®**  
*Anticavity  
Fluoride Toothpaste*

**ADA**  
**Accepted**  
**American**  
**Dental**  
**Association®**

*NET WT 4.0 OZ (113 g)*

*Cavity  
Protection*

*Strengthens Teeth  
with Active Fluoride*

*Great Regular Flavor*

# Colgate®

Anticavity Fluoride Toothpaste



NET WT 4.0 OZ (113 g)

## Cavity Protection

Strengthens Teeth with Active Fluoride

Great Regular Flavor

# Colgate®

Anticavity Fluoride Toothpaste



NET WT 4.0 OZ (113 g)

## Cavity Protection

Strengthens Teeth with Active Fluoride

Great Regular Flavor

### Drug Facts

**Active ingredient** Purpose  
Sodium monofluorophosphate 0.76% (0.15% w/v fluoride ion).....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** dicalcium phosphate dihydrate, water, glycerin, sodium lauryl sulfate, cellulose gum, flavor, tetrasodium pyrophosphate, sodium saccharin

**Questions?** 1-800-468-6502



The ADA Council on Scientific Affairs' Acceptance of Colgate Cavity Protection is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed.

www.colgate.com

Made in Mexico

GLUTEN FREE



Dist. by:  
**COLGATE-PALMOLIVE COMPANY**  
New York, NY 10022 U.S.A.

# Colgate®

## Cavity Protection

Clinically proven to help strengthen teeth and leave your mouth feeling fresh and clean.



Great Mint Taste

Cleans Teeth Thoroughly

Active Fluoride Formula Strengthens Teeth

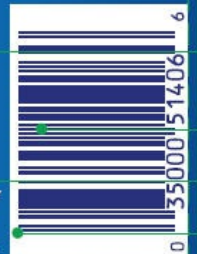
Fights Cavities

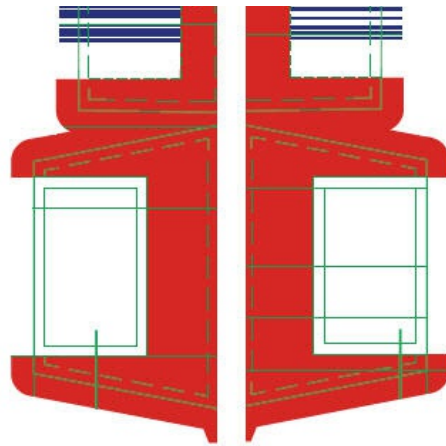
SAVE WATER



www.colgate.com/savewater

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





## COLGATE GREAT REGULAR FLAVOR

sodium monofluorophosphate paste, dentifrice

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:35000-913 |
| <b>Route of Administration</b> | DENTAL         |                           |               |

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

| Ingredient Name   | Strength        |
|---|-----------------|
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                           | 49.14 mg in 1 g |
| <b>WATER</b> (UNII: 059QF0KO0R)   |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |                 |
| <b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)             |                 |
| <b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311) |                 |
| <b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)                            |                 |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)                                |                 |

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | WHITE | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   | MINT  | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---------------------|----------------------|--------------------|
|---|-----------|---------------------|----------------------|--------------------|

|    |                  |  |            |  |
|----|------------------|--|------------|--|
| 1  | NDC:35000-913-20 | 24 g in 1 TUBE; Type 0: Not a Combination Product    | 11/05/2005 |  |
| 2  | NDC:35000-913-33 | 1 in 1 CARTON  | 11/05/2005 |  |
| 2  |                  | 36.8 g in 1 TUBE; Type 0: Not a Combination Product  |            |  |
| 3  | NDC:35000-913-69 | 1 in 1 CARTON  | 11/05/2005 |  |
| 3  |                  | 113 g in 1 TUBE; Type 0: Not a Combination Product   |            |  |
| 4  | NDC:35000-913-46 | 1 in 1 CARTON  | 11/05/2005 |  |
| 4  |                  | 130 g in 1 TUBE; Type 0: Not a Combination Product   |            |  |
| 5  | NDC:35000-913-60 | 170 g in 1 TUBE; Type 0: Not a Combination Product   | 11/05/2005 |  |
| 6  | NDC:35000-913-64 | 1 in 1 CARTON  | 11/05/2005 |  |
| 6  |                  | 181 g in 1 TUBE; Type 0: Not a Combination Product   |            |  |
| 7  | NDC:35000-913-82 | 1 in 1 CARTON  | 11/05/2005 |  |
| 7  |                  | 232 g in 1 TUBE; Type 0: Not a Combination Product   |            |  |
| 8  | NDC:35000-913-04 | 4.25 g in 1 POUCH; Type 0: Not a Combination Product | 11/05/2005 |  |
| 9  | NDC:35000-913-79 | 1 in 1 CARTON  | 11/05/2005 |  |
| 9  |                  | 79 g in 1 TUBE; Type 0: Not a Combination Product    |            |  |
| 10 | NDC:35000-913-93 | 99 g in 1 TUBE; Type 0: Not a Combination Product    | 11/05/2005 |  |
| 11 | NDC:35000-913-48 | 1 in 1 CARTON  | 11/05/2005 |  |
| 11 |                  | 226 g in 1 TUBE; Type 0: Not a Combination Product   |            |  |
| 12 | NDC:35000-913-01 | 1 in 1 CARTON  | 11/05/2005 |  |
| 12 |                  | 28 g in 1 TUBE; Type 0: Not a Combination Product    |            |  |
| 13 | NDC:35000-913-58 | 1 in 1 CARTON  | 11/05/2005 |  |
| 13 |                  | 70 g in 1 TUBE; Type 0: Not a Combination Product    |            |  |
| 14 | NDC:35000-913-92 | 1 in 1 CARTON  | 11/05/2005 |  |
| 14 |                  | 141 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                                  | 11/05/2005           |                    |

**Labeler** - Colgate-Palmolive Company (001344381)

Revised: 12/2019

Colgate-Palmolive Company