

# **COLGATE OPTIC WHITE SPARKLING- 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.*

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## **Colgate® Optic White® Sparkling**

### **Drug Facts**

#### **Active ingredient**

Sodium Monofluorophosphate 0.76% (0.13% 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**

Propylene Glycol, Calcium Pyrophosphate, PEG/PPG-116/66 Copolymer, PEG-12, Glycerin, PVP, Silica, Flavor, Tetrasodium Pyrophosphate, Sodium Lauryl Sulfate,

Hydrogen Peroxide, Disodium Pyrophosphate, Sodium Saccharin, Sucralose, BHT.

**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

OPTIC

WHITE®

LOVERS

REMOVES STUBBORN,  
DARK STAINS

DEEPLY WHITENS  
BEYOND THE SURFACE

FRESH MINT

NET WT 4.6 OZ (130 g)

ENAMEL SAFE

PS0033822

OPTIC WHITE



LOVERS

Some people may experience tooth sensitivity or gum discomfort when using whitening products. This discomfort is temporary and not harmful. If you experience more than mild tooth sensitivity, stop use and consult your dentist.

|  |                                    |
|--|------------------------------------|
| <b>Drug Facts (continued)</b>  |                                    |
| <b>Directions</b><br>brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or physician<br>use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)<br>ask a dentist or physician     | <b>Children under 2 years</b>      |
| <b>Warnings</b><br>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.   | <b>Children 2 to 6 years</b>       |
| <b>Use</b> helps protect against cavities  | <b>Children 6 to 11 years</b>      |
| <b>Active ingredient</b><br>Sodium Monofluorophosphate<br>0.78% (0.13% w/v fluoride ion)   | <b>Children 12 years and older</b> |
| <b>Purpose</b><br>Anticavity   | <b>Adults</b>                      |
| <b>Inactive ingredients</b> Propylene Glycol, Calcium Pyrophosphate, PEG-PPG-11-6-6 Copolymer, PEG-12, Glycerin, PVP, Silica, Flavor, Tetraacetic Pyrophosphate, Sodium Lauryl Sulfate, Hydrogen Peroxide, Disodium Pyrophosphate, Sodium Saccharin, Sorbitol, Sucralose, BHT. |                                    |

Colgate  
Anticavity Fluoride Toothpaste

Colgate  
OPTIC WHITE

Colgate  
Anticavity Fluoride Toothpaste

OPTIC WHITE



OPTIC WHITE

|  |
|--|
| <b>Drug Facts</b>  |
| <b>Active ingredient</b><br>Sodium Monofluorophosphate<br>0.78% (0.13% w/v fluoride ion)   |
| <b>Purpose</b><br>Anticavity   |
| <b>Use</b> helps protect against cavities  |
| <b>Warnings</b><br>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. |

LOVERS

MAINTAIN A BRIGHT, WHITE SMILE WHILE STILL ENJOYING THE THINGS YOU LOVE WITH OPTIC WHITE® LOVERS LINE.

LOVERS

REMOVES STUBBORN, DARK STAINS

CLINICALLY PROVEN TO REMOVE DEEP STAINS

REMOVES STUBBORN, DARK STAINS

CONTAINS DENTIST RECOMMENDED HYDROGEN PEROXIDE



DEEPLY WHITENS BEYOND THE SURFACE

DEEPLY WHITENS BEYOND THE SURFACE



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

smartlabel app enabled



NET WT 4.6 OZ (130 g) ENAMEL SAFE

NET WT 4.6 OZ (130 g) ENAMEL SAFE

Colgate

LOT:  
EXP:



# COLGATE OPTIC WHITE SPARKLING

sodium monofluorophosphate paste, dentifrice

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:35000-758 |
| <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 mg<br>in 1 g |

## Inactive Ingredients

| Ingredient Name                                     | Strength |
|---|----------|
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)          |          |
| <b>CALCIUM PYROPHOSPHATE</b> (UNII: X69NU20D19)     |          |
| <b>PEG/PPG-116/66 COPOLYMER</b> (UNII: JPOCK963E0)  |          |
| <b>POLYETHYLENE GLYCOL 600</b> (UNII: NL4J9F21N9)   |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                  |          |
| <b>POVIDONE K15</b> (UNII: E54VE15114)              |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)           |          |
| <b>SODIUM PYROPHOSPHATE</b> (UNII: O352864B8Z)      |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)     |          |
| <b>HYDROGEN PEROXIDE</b> (UNII: BBX060AN9V)         |          |
| <b>SODIUM ACID PYROPHOSPHATE</b> (UNII: H5WWD9LZUD) |          |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)          |          |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)                 |          |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)  |          |

## 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:35000-758-94 | 1 in 1 CARTON                                      | 07/27/2022           |                    |
| 1 |                  | 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 FINAL | part355                                  | 07/27/2022           |                    |

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

Revised: 8/2022

Colgate-Palmolive Company