

OPAL BY OPALESCENCE ORIGINAL- sodium fluoride gel, dentifrice
Ultradent Products, Inc.

Opal™ by Opalescence® Original

Drug Facts

Active Ingredients

Sodium Fluoride 0.25% w/w

Purpose

Anticavity

Uses

Aids in the prevention of dental decay.

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 doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 2 years of age: Consult a dentist or doctor.

Other Information

- Do not use if tamper-evident seal is broken
- Store at room temperature
- Contains FD&C Yellow No. 5 (tartrazine) as a color additive

Inactive Ingredients

Glycerin, Water (Aqua), Silica, Sorbitol, Xylitol, Methyl Salicylate (flavor), Poloxamer 407, Sodium Lauryl Sulfate, Carbomer, Cool Mint Flavor, FD&C Blue #1 (CI 42090), FD&C Yellow #5 (CI 19140), Wintermint Flavor, Sodium Benzoate, Sodium Hydroxide, Sucralose, Xanthan Gum

Questions or comments

Call toll-free **1.800.496.8330**

PRINCIPAL DISPLAY PANEL - 4.7 OZ Tube Carton

opal™
by Opalescence®

Whitening
Toothpaste

ORIGINAL
COOL MINT

FLUORIDE TOOTHPASTE
NET WT. 4.7 OZ



DEVELOPED BY A DENTIST



ACTIVELY REMOVES SURFACE STAINS for whiter teeth



FORMULATED TO STRENGTHEN ENAMEL and help prevent cavities



GENTLE ENOUGH for everyday use



UNIQUE COOL MINT FLAVOR for fresh breath that lasts



AVAILABLE IN A SENSITIVITY FORMULA to treat sensitive teeth

glow with us at opalsmile.com

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Whitening Toothpaste

ORIGINAL



COOL MINT

FLUORIDE TOOTHPASTE NET WT. 4.7 OZ

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Manufactured for: Ultradent Products, Inc., South Jordan, UT 84095, USA 1011641AR02 032223





OPAL BY OPALESCENCE ORIGINAL

sodium fluoride gel, dentifrice

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51206-312 |
| Route of Administration | DENTAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) | FLUORIDE ION | 1.1 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0K00R) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SORBITOL (UNII: 506T60A25R) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| METHYL SALICYLATE (UNII: LAV5U5022Y) | |
| POLOXAMER 407 (UNII: TUF21VW3M2) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |
| CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---------------|---------------------|----------------------|--------------------|
| | NDC:51206-312 | | | |

| | | | | |
|---|------------------|--|------------|------------|
| 1 | NDC:51206-312-02 | 3 in 1 PACKAGE, COMBINATION | 11/19/2023 | 02/21/2029 |
| 1 | | 1 in 1 CARTON | | |
| 1 | | 133 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:51206-312-01 | 1 in 1 CARTON | 11/19/2023 | 02/21/2029 |
| 2 | | 133 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 Drug | M021 | 11/19/2023 | |

Labeler - Ultradent Products, Inc. (013369913)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|---|
| Ultradent Products, Inc. | | 013369913 | manufacture(51206-312) , analysis(51206-312) , label(51206-312) , pack(51206-312) |

Revised: 6/2025

Ultradent Products, Inc.