

OPAL BY OPALESCENCE SENSITIVITY- potassium nitrate and sodium fluoride gel, dentifrice
Ultradent Products, Inc.

Opal™ by Opalescence® Sensitivity

Drug Facts

Active Ingredients	Purpose
Potassium Nitrate 5% w/w	Antihypersensitivity
Sodium Fluoride 0.25% w/w	Anticavity

Uses

- Helps reduce painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.
- Aids in the prevention of dental cavities.

Warnings

Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. See your dentist if the problem persists or worsens. Do not use this product longer than 4 weeks unless recommended by a dentist or doctor.

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 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. Make sure to brush all sensitive areas of the teeth.
- Children under 12 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

Water (Aqua), Silica, Xylitol, Glycerin, Sorbitol, Poloxamer 407, Methyl Salicylate (flavor), 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

SENSITIVITY
RELIEF

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



CONTAINS AN ACTIVE INGREDIENT to help treat sensitive teeth

glow with us at opalsmile.com

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Whitening Toothpaste

SENSITIVITY RELIEF

COOL MINT

FLUORIDE TOOTHPASTE NET WT. 4.7 OZ

opal by Opalescence

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Manufactured for: Ultradent Products, Inc., South Jordan, UT 84095, USA 1011643AR02 032223





OPAL BY OPALESCENCE SENSITIVITY

potassium nitrate and sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51206-311
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
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

		Marketing Start	Marketing End
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51206-311-02	3 in 1 PACKAGE, COMBINATION	11/19/2023	
1	NDC:51206-311-01	1 in 1 CARTON		
1		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	M022	11/19/2023	

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	analysis(51206-311) , manufacture(51206-311) , label(51206-311) , pack(51206-311)

Revised: 3/2024

Ultradent Products, Inc.