OPALESCENCE WHITENING SENSITIVITY RELIEF- potassium nitrate and sodium fluoride gel, dentifrice
Ultradent Products, Inc.

Opalescence™ Whitening Toothpaste Sensitivity Relief

Drug Facts

Active Ingredients

Potassium Nitrate 5% w/w

Sodium Fluoride 0.24% w/w

Purpose

Antihypersensitivity

Anticavity

Uses

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

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 yeasrs 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

Aqua (Water), Silica, Xylitol, Glycerin, Sorbitol, Poloxamer 407, Methyl Salicylate, Sodium Lauryl Sulfate, Carbomer, FD&C Blue No. 1 (CI 42090), FD&C Yellow No. 5 (CI 19140), Flavor (Aroma), Sodium Benzoate, Sodium Hydroxide, Sucralose, Xantham Gum

Questions or comments

Call toll-free 1.800.552.5512

Principal Display Panel - 4.7 oz Tube Carton

Opalescence Whitening Toothpaste

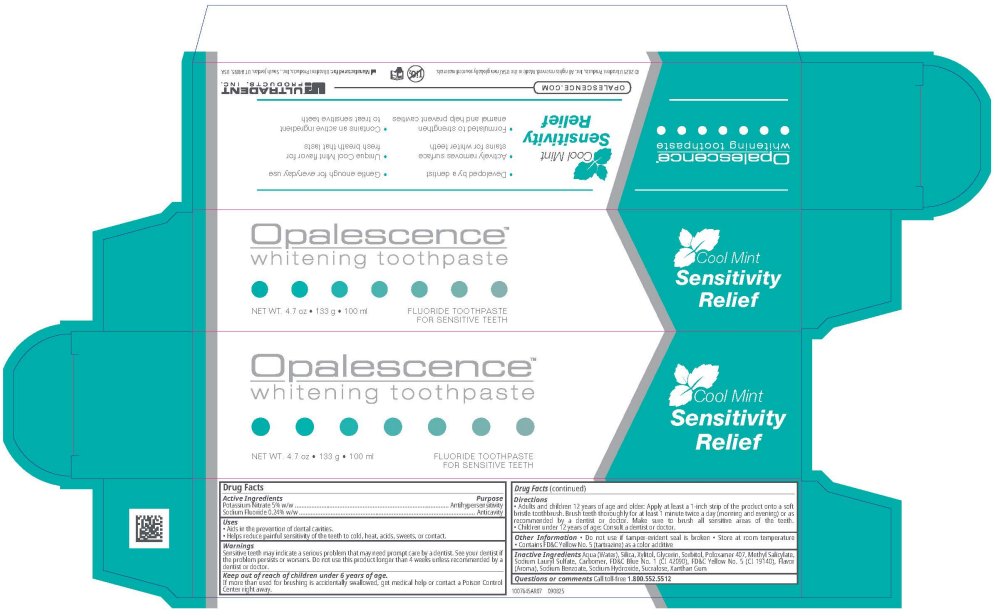
Sensitivity Relief

Cool Mint

NET WT. 4.7 oz * 133 g 8 100 ml

FLUORIDE TOOTHPASTE

FOR SENSITIVE TEETH



OPALESCENCE WHITENING SENSITIVITY RELIEF

potassium nitrate and sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51206-315
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CARBOMER (UNII: 0A5MM307FC)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SORBITOL (UNII: 506T60A25R)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
AQUA (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT (Cool Mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51206-315-01	1 in 1 CARTON	10/08/2025	
1		133 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51206-315-02	12 in 1 PACKAGE, COMBINATION	10/08/2025	
2		1 in 1 CARTON		
2		133 g in 1 TUBE; Type 0: Not a Combination Product		

3	NDC:51206-315-03	1 in 1 CARTON	10/08/2025	
3		28 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51206-315-04	24 in 1 PACKAGE, COMBINATION	10/08/2025	
4		1 in 1 CARTON		
4		28 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:51206-315-05	48 in 1 PACKAGE, COMBINATION	10/08/2025	
5		1 in 1 CARTON		
5		28 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	10/08/2025	

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc		013369913	label(51206-315) , analysis(51206-315) , manufacture(51206-315) , pack(51206-315)

Revised: 12/2025 Ultradent Products, Inc.