

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

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**Opalescence™ Sensitivity Relief Whitening Toothpaste**

**Drug Facts**

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
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, Flavor (Aroma), Poloxamer 407, Sodium Lauryl Sulfate, Carbomer, Sodium Benzoate, Sodium Hydroxide, Sucralose, Xanthan

Gum, FD&C Blue No. 1 (CI 42090), FD&C Yellow No. 5 (CI 19140)

**Questions or comments**

Call toll-free **1.800.552.5512**

**Manufactured by:**Ultradent Products, Inc., South Jordan, UT 84095, USA

**PRINCIPAL DISPLAY PANEL - 133 g Tube Carton**

**Opalescence™**  
whitening toothpaste

*Cool Mint*

***Sensitivity  
Relief***

NET WT. 4.7 oz • 133 g • 100 ml

FLUORIDE TOOTHPASTE  
FOR SENSITIVE TEETH

ULTRADENT  
PRODUCTS, INC.



- Developed by a dentist
- Formulated to strengthen enamel and help prevent cavities
- Active removes surface stains for whiter teeth
- Unique Cool Mint flavor for fresh breath that lasts
- Contains an active ingredient to help treat sensitive teeth
- Gentle enough for everyday use



OPALESCENCE.COM

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Opalescence  
whitening toothpaste

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## whitening toothpaste



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FOR SENSITIVE TEETH



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### Drug Facts (continued)

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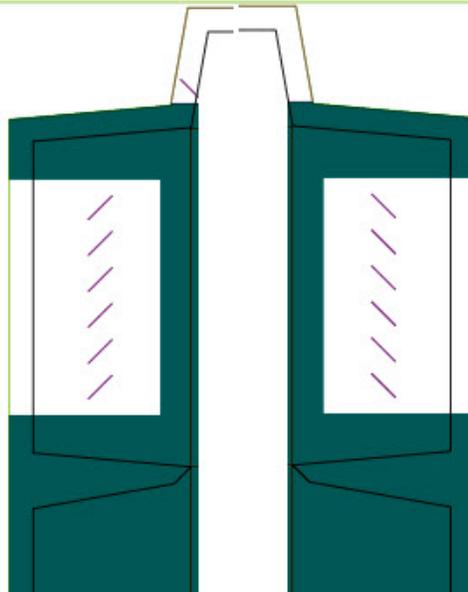
**Other Information**

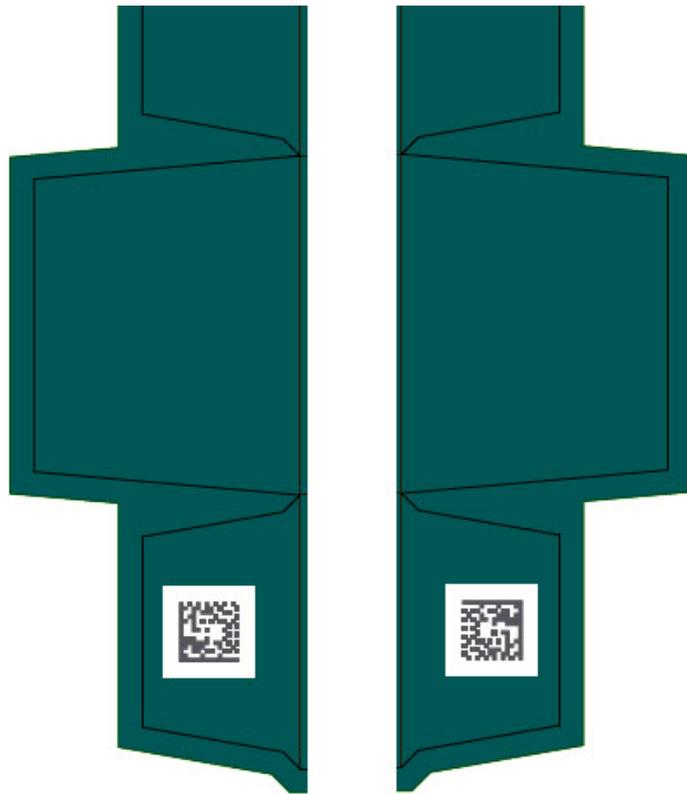
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## OPALESCENCE SENSITIVITY RELIEF WHITENING

potassium nitrate and sodium fluoride gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51206-308
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)	POTASSIUM NITRATE	50 mg in 1 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	1.1 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	

**SODIUM LAURYL SULFATE** (UNII: 368GB5141J)

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	MINT (Cool Mint)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51206-308-01	1 in 1 CARTON	11/30/2015	10/13/2030
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51206-308-05	24 in 1 PACKAGE, COMBINATION	11/30/2015	10/13/2030
2		1 in 1 CARTON		
2		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51206-308-02	1 in 1 CARTON	11/30/2015	10/13/2030
3		133 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51206-308-03	3 in 1 PACKAGE, COMBINATION	11/30/2015	10/13/2030
4		1 in 1 CARTON		
4		133 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:51206-308-04	12 in 1 PACKAGE, COMBINATION	11/30/2015	10/13/2030
5		1 in 1 CARTON		
5		133 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:51206-308-06	6 in 1 PACKAGE, COMBINATION	11/30/2015	10/13/2030
6		1 in 1 CARTON		
6		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	11/30/2015	

**Labeler** - Ultradent Products, Inc. (013369913)

**Establishment**

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	manufacture(51206-308) , analysis(51206-308) , label(51206-308) , pack(51206-308)

Revised: 11/2025

Ultradent Products, Inc.