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

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.

Opalescence™ Sensitivity Relief Whitening Toothpaste

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, 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

Opalescence™
whitening toothpaste

NET WT. 4.7 oz • 133 g • 100 ml

FLUORIDE TOOTHPASTE
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Cool Mint
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Opalescence™
whitening toothpaste

Cool Mint
Sensitivity Relief

- 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

OPALESCENCE.COM

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

ULTRADENT PRODUCTS, INC.

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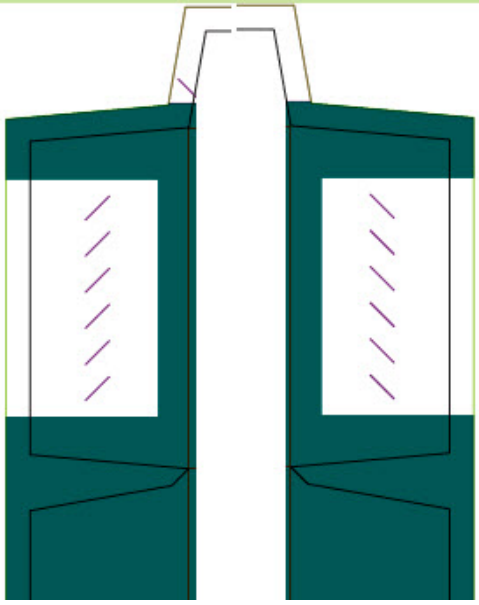

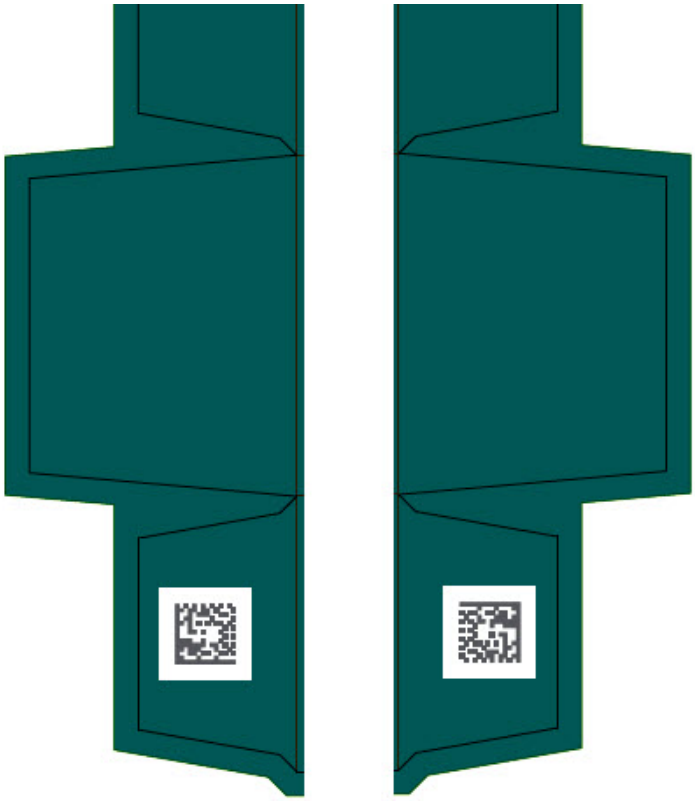

OPALESCENCE SENSITIVITY RELIEF WHITENING

potassium nitrate and sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51206-308
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**
Glycerin (UNII: PDC6A3C0OX)	
Xanthan Gum (UNII: TTV12P4NEE)	
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Xylitol (UNII: VCQ006KQ1E)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sucralose (UNII: 96K6UQ3ZD4)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Methyl Salicylate (UNII: LAV5U5022Y)	

Sodium Lauryl Sulfate (UNII: 368GB5141J)	

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:51206-308-01	1 in 1 CARTON	11/30/2015	
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	
2	NDC:51206-308-01	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	
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	
4	NDC:51206-308-02	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	
5	NDC:51206-308-02	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	
6	NDC:51206-308-02	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 NOT FINAL	part356	11/30/2015	

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
OraTech, LLC		827869285	MANUFACTURE(51206-308) , ANALYSIS(51206-308) , LABEL(51206-308) , PACK(51206-308)

Revised: 2/2022 Ultradent Products, Inc.