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

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 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		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		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		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		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: 2/2024 Ultradent Products, Inc.