OPALESCENCE WHITENING COOL MINT- sodium fluoride gel, dentifrice
Ultradent Products, Inc.

Opalescence™ Whitening Toothpaste Original Cool Mint

Drug Facts

Active Ingredients

Sodium Fluoride 0.24% w/w

Purpose

Anticavity

Uses

Aids in the prevention of dental decay

Warnings

Warnings

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 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.
- Children under 2 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

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

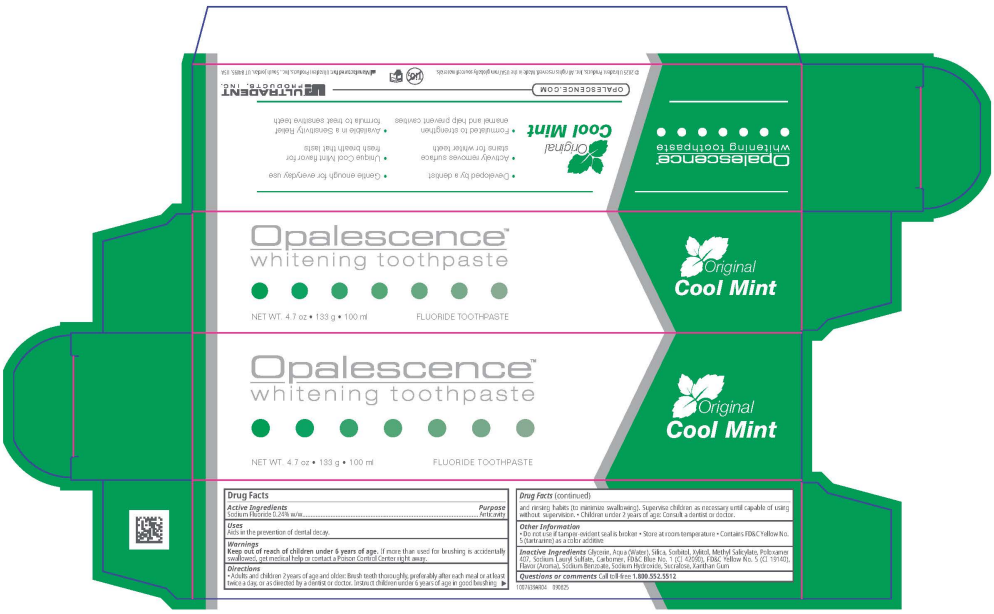
Opalescence Whitening Toothpaste

Original

Cool Mint

Fluoride Toothpaste

NET WT. 4.7 oz



OPALESCENCE WHITENING COOL MINT

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51206-314
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
AQUA (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
CARBOMER (UNII: 0A5MM307FC)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XYLITOL (UNII: VCQ006KQ1E)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	green	**Score**	
Shape		**Size**	
Flavor	MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51206-314-01	1 in 1 CARTON	09/23/2025	
1		133 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51206-314-03	1 in 1 CARTON	09/23/2025	
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51206-314-02	12 in 1 PACKAGE, COMBINATION	09/23/2025	
3		1 in 1 CARTON		
3		133 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51206-314-04	24 in 1 PACKAGE, COMBINATION	09/23/2025	
4		1 in 1 CARTON		
4		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	M021	09/23/2025	

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	manufacture(51206-314) , analysis(51206-314) , label(51206-314) , pack(51206-314)

Revised: 12/2025 Ultradent Products, Inc.