OPAL BY OPALESCENCE ORIGINAL- sodium fluoride gel, dentifrice
Ultradent Products, Inc.

Opal™ by Opalescence ®Original

Drug Facts

Active Ingredients

Sodium Fluoride 0.25% w/w

Purpose

Anticavity

Uses

Aids in the prevention of dental decay.

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, Water (Aqua), Silica, Sorbitol, Xylitol, Methyl Salicylate (flavor), Poloxamer 407, Sodium Lauryl Sulfate, Carbomer, Cool Mint Flavor, FD&C Blue #1 (CI 42090), FD&C Yellow #5 (CI 19140), Wintermint Flavor, Sodium Benzoate, Sodium Hydroxide, Sucralose, Xantham Gum

Questions or comments

Call toll-free **1.800.496.8330**

PRINCIPAL DISPLAY PANEL - 4.7 OZ Tube Carton

opal™
by Opalescence ®

Whitening
Toothpaste

ORIGINAL
COOL MINT

FLUORIDE TOOTHPASTE
NET WT. 4.7 OZ

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

AVAILABLE IN A SENSITIVITY FORMULA
to treat sensitive teeth

glow with us at
opalsmile.com

opal™ by Opalescence

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ORIGINAL

COOL MINT

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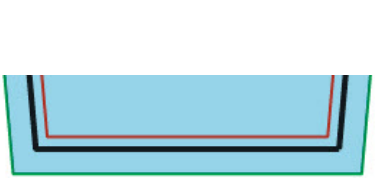
Manufactured for:
Ultradent Products, Inc., South Jordan, UT 84095, USA 1011641AR02 032223



OPAL BY OPALESCENCE ORIGINAL

sodium fluoride gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51206-312
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**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SORBITOL (UNII: 506T60A25R)	
XYLITOL (UNII: VCQ006KQ1E)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
	NDC:51206-312			

1	NDC:51206-312-02	3 in 1 PACKAGE, COMBINATION	11/19/2023	
1	NDC:51206-312-01	1 in 1 CARTON		
1		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	M021	11/19/2023	

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	manufacture(51206-312) , analysis(51206-312) , label(51206-312) , pack(51206-312)

Revised: 3/2024 Ultradent Products, Inc.