

OPAL BY OPALESCENCE COMPLETE- opal by opalescence complete gel, dentifrice
Ultradent Products, Inc.

Keep out of reach of children under 6 years of age. If more than used for burshing is accidentally swallowed, get medical help or contact a Poison Control Center right away.



OPAL BY OPALESCENCE COMPLETE			
opal by opalescence complete gel, dentifrice			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51206-313
Route of Administration	DENTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU4080)		FLUORIDE ION	1.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
FLAVOR SPICE MINT N&A110589 (UNII: KG6KU384XW)	
ZINC CITRATE (UNII: K72I3DEX9B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM PYROPHOSPHATE (UNII: O352864B8Z)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SORBITOL (UNII: 506T60A25R)	

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:51206-313-01	1 in 1 CARTON	10/21/2024	
1		133 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51206-313-02	12 in 1 PACKAGE, COMBINATION	10/21/2024	
2		1 in 1 CARTON		
2		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	10/21/2024	

Labeler - Ultradent Products, Inc. (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	analysis(51206-313) , manufacture(51206-313) , label(51206-313) , pack(51206-313)

Revised: 12/2024

Ultradent Products, Inc.