OPALESCENCE WHITENING- sodium fluoride gel, dentifrice
Ultradent Products, Inc

Opalescence™
whitening toothpaste

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, 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 - 100 ml Tube Box

Opalescence™
whitening toothpaste

NET WT. 4.7 oz • 133 g • 100 ml
FLUORIDE TOOTHPASTE

Original
Cool Mint

OPALESCENCE WHITENING

sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51206-302
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
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
XYLITOL (UNII: VCQ006KQ1E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

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:51206-302-07	1 in 1 BOX	07/01/1994	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51206-302-10	24 in 1 PACKAGE, COMBINATION	06/01/2016	
2		1 in 1 BOX		
2		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51206-302-06	1 in 1 BOX	07/01/1994	
3		133 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:51206-302-08	3 in 1 PACKAGE, COMBINATION	06/01/2016	
4		1 in 1 BOX		
4		133 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:51206-302-09	12 in 1 PACKAGE, COMBINATION	06/01/2016	
5		1 in 1 BOX		
5		133 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:51206-302-11	6 in 1 PACKAGE, COMBINATION	08/24/2020	
6		1 in 1 BOX		
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	M021	07/01/1994	

Labeler - Ultradent Products, Inc (013369913)

Establishment

Name	Address	ID/FEI	Business Operations
Ultradent Products, Inc.		013369913	manufacture(51206-302) , analysis(51206-302) , label(51206-302) , pack(51206-302)

Revised: 2/2024

Ultradent Products, Inc