

**ALORA SENSITIVITY- potassium nitrate and sodium fluoride gel, dentifrice
Amazon, Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

**Alora™
Sensitivity Toothpaste**

Drug Facts

Active Ingredients	Purpose
Sodium Fluoride 0.25% w/w	Anticavity
Potassium Nitrate 5% w/w	Anti-sensitivity

Uses

- Aids in the prevention of dental cavities.
- Helps reduce painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.

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. 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

Carboxypolymethylene, FD&C Blue #1 (CI 42090), FD&C Yellow #5 (CI 19140), Flavor (aroma), Glycerin, Methyl Salicylate, Poloxamer 407, Potassium Nitrate, Silicon Dioxide, Sodium Benzoate, Sodium Hydroxide, Sodium Lauryl Sulfate, Sorbitol, Sucralose, Water (aqua), Xanthan Gum, Xylitol.

Questions or comments

Call toll-free **1-800-526-6880**

Manufactured by: OraTech, LLC
10075 South Jordan Gateway, South Jordan, UT 84095

PRINCIPAL DISPLAY PANEL - 113 g Tube Carton

ALORA™

WHITENING
TOOTHPASTE

SENSITIVITY

MINT

NET WT. 4 oz • 113 g

ALORA SENSITIVITY

potassium nitrate and sodium fluoride gel, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72288-309
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	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
Water (UNII: 059QF0KO0R)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
Poloxamer 407 (UNII: TUF2IVW3M2)	
Methyl Salicylate (UNII: LAV5U5022Y)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Xanthan Gum (UNII: TTV12P4NEE)	
Sodium Benzoate (UNII: OJ245FE5EU)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
Sodium Hydroxide (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
Sucralose (UNII: 96K6UQ3ZD4)	

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:72288-309-02	3 in 1 PACKAGE, COMBINATION	10/01/2019	
1	NDC:72288-309-01	1 in 1 CARTON		
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72288-309-03	6 in 1 PACKAGE, COMBINATION	10/01/2019	
2	NDC:72288-309-01	1 in 1 CARTON		

2	28.35 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 NOT FINAL	part356	10/01/2019	

Labeler - Amazon, Inc (128990418)

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