

# **UNIVERSAL SENSITIVE ANTI-CAVITY FLUORIDE- potassium nitrate and sodium fluoride paste**

**Universal Distribution Center LLC**

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**UNIVERSAL SENSITIVE ANTI-CAVITY FLUORIDE TOOTHPASTE**

## **Active Ingredients**

Potassium Nitrate 5%

Sodium Fluoride- 0.32% (0.15% w/v fluoride ion)

## **Purpose**

Antihypersensitivity

Anticavity

## **Uses**

- builds increasing protection against painful sensitivity of teeth due to cold, heat, acids, sweets or contact.
- aids in the prevention of dental cavities.

## **Warning**

### **When using this product**

- if pain\ sensitivity still persists after 4 weeks of use, please visit your dentist.

### **Stop and ask a dentist**

- if the problem persists or worsens.

Sensitivity teeth may indicate a serious problem that may need prompt care by a dentist.

### **Keep out of reach of children**

- If accidentally swallowed more than used for brushing, seek professional help or contact a Poison Control Center immediately.

## **Directions**

- adults and children 12 years of age and older
- apply at least a 1-inch strip of product onto soft bristle toothbrush
- brush teeth thoroughly for at least 1 minute twice a day (morning and evening), and not more than 3 times day, or as recommended by a dentist or doctor.
- make sure to brush all sensitive areas of the teeth. Minimize swallowing. Spit out after brushing.

**Children under 12 years of age:** Consult a dentist or doctor.

## **Other information**

- store in a cool, dry place.

## **Inactive Ingredients**

Sorbitol, Water, Silica, Sodium lauryl sulfate, Xanthan gum, Sodium saccharin, Sodium benzoate, Sodium carboxy methyl cellulose, Titanium dioxide, Flavor, D&C yellow#10,

FD&C blue#1

**PRINCIPAL DISPLAY PANEL**

**UNIVERSAL SENSITIVE ANTI-CAVITY FLUORIDE TOOTHPASTE**



<b>UNIVERSAL SENSITIVE ANTI-CAVITY FLUORIDE</b>			
potassium nitrate and sodium fluoride paste			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52000-109
<b>Route of Administration</b>	DENTAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>POTASSIUM NITRATE</b> (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)		POTASSIUM NITRATE	5 g in 100 g
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)		FLUORIDE ION	0.15 g in 100 g
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
<b>SORBITOL</b> (UNII: 506T60A25R)			
<b>WATER</b> (UNII: 059QF0KO0R)			
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)			
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)			
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)			
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)			
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)			
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)			

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52000-109-01	122 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	05/20/2020	

**Labeler** - Universal Distribution Center LLC (019180459)

Revised: 11/2023

Universal Distribution Center LLC