

## **4X MEDICATED TOOTHACHE AND GUM CREAM- benzocaine cream HEB**

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**5820611 4x Med Cream**

Active ingredients Purpose

Benzalkonium chloride 0.13% . . . Oral antiseptic

Benzocaine 20% . . . . . Oral pain reliever

Menthol 0.26% . . . . . Oral pain reliever

Zinc chloride 0.15% . . . . . Oral astringent

Oral antiseptic

Oral pain reliever

Oral pain reliever

Oral astringent

### **Use**

for the temporary relief of pain due to minor irritation of injury of the mouth and gums

- first aid to help prevent infection in minor oral irritation

**Methemoglobinemia warning:** use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache \* rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

**Allergy alert:** do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

### **Do not use**

- more than directed
- for more than 7 days unless told to do so by a dentist or doctor
- for teething
- in children under 2 years of age

### **Stop use and ask a doctor if**

- symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain or redness persists or worsens

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- cut open tip of tube on score mark
- **adults and children 2 years of age and older:** apply to affected area up to 4 times daily or as directed by a dentist or doctor
- **children under 12 years of age:** ask doctor before use. Should be supervised in the use of this product
- **children under 2 years of age:** do not use

ammonium glycyrrhizate, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid, titanium dioxide

**Other information**

- do not use if tip is cut prior to opening
- avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying



benzocaine cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-116
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.25 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	

## Product Characteristics

<b>Color</b>	white (Cloudy)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	WINTERGREEN	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-116-69	1 in 1 CARTON	06/02/2020	
1		9.4 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	M022	06/02/2020	

**Labeler** - HEB (007924756)

**Registrant** - Lornamead Products (119559733)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead Products		119559733	manufacture(37808-116) , pack(37808-116)

Revised: 1/2026

HEB