

## **3X MEDICATED MOUTH SORE GEL- benzocaine gel HEB**

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**5820619 3x Med Gel**

### Active ingredients Purpose

Benzocaine 20% . . . . .Oral pain reliever

Menthol 0.1% . . . . . Oral pain reliever

Zinc chloride 0.15% . . . .Oral astringent

### **Uses**

temporarily relieves pain caused by \* canker sores \* cold sores \* fever blisters \* minor irritation or injury of the mouth and gums

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**

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 \* swelling, rash or fever develops \* irritation, pain or redness persists or worsens \* symptoms do not improve in 7 days \* allergic reaction occurs

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

### **Directions**

Directions \* cut open tip of tube on score mark \* do not use if tip is cut prior to opening \* 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 should be supervised in the use of this product \* children under 2 years of age: do not use

allantoin, carbomer, disodium EDTA, flavor, polyethylene glycol, polysorbate 60, propylene glycol, pvp, sodium saccharin, sorbic acid, stearyl alcohol, water

1.000 X 1.000 X 4.313 - PRINTSIDE  
 FOIL S170272 - 3/9/17



LORNAMEAD, INC.		PROJECT INFO   PRODUCTION NOTES										
DATE:	APRIL 22, 2020	<table border="1"> <tr> <td>CYAN</td> <td>MAGENTA</td> <td>YELLOW</td> <td>BLACK</td> </tr> <tr> <td>WHITE</td> <td>PMS 661</td> <td></td> <td></td> </tr> </table>	CYAN	MAGENTA	YELLOW	BLACK	WHITE	PMS 661			<b>APPROVALS</b> CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____	
CYAN	MAGENTA		YELLOW	BLACK								
WHITE	PMS 661											
PROJECT:	HEB 3X MEDICATED MOUTH SORE GEL CARTON											
ITEM #:	2821619R1											
DIELINE #:	5170272											
SIZE:	1.000" X 1.000" X 4.313"											
FILE NAME:	HEB_3XMEDICATED_MOUTHSOREGEL_CTN_2821619R1-01.LAI											
PRINTER:	MODPAC											
NOTE(S):												

# 3X MEDICATED MOUTH SORE GEL

benzocaine gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-691
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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	0.1 g in 100 g
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	yellow (Clear to yellow tint)	<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:37808-691-	1 in 1 CARTON	06/02/2020	

1	19	1 III 1 CARTON	06/02/2020	
1		9.4 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M022		06/02/2020	

**Labeler -** HEB (007924756)

**Registrant -** Lornamead (126440440)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(37808-691)

Revised: 1/2025

HEB