

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

### **Rite Aid**

*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.*

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### **5820617 RA 3x Gel**

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: do not use this product if you have a history of allergy to local anesthetics such as procain, 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**

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 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



## 3X MEDICATED MOUTH SORE GEL

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-6170
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.1 g in 100 g
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	

<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01Z NK31)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	

### 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:11822-6170-9	1 in 1 CARTON	06/05/2020	
1		11.9 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	06/05/2020	

**Labeler** - Rite Aid (014578892)

**Registrant** - Lornamead (080046418)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-6170)