

## **4X MEDICATED SEVERE TOOTHACHE AND GUM CREAM- benzocaine cream 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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### Active Ingredient Purpose

Belkonium chloride 0.13% .... Oral antiseptic  
Benzocaine 20% ..... Oral pain reliever  
Menthol 0.26% ..... Oral pain reliever  
Zinc chloride 0.15% ..... Oral astringent

### **Use**

Use \* for the temporary relief of pain due to toothaches \* to help protect against infection of minor oral irritation

### Warnings

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces teh 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 \* swelling, rash or fever develops \* irritation, pain or redness persists or worsens \* symtoms 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 \* dults and children 2 years of age and older; apply a small amount of product to the cavity and around teh gum surrounding the teeth. Use 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

Other information \* do not use if the tip is cut prior to opening \* this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted \* do not use continuously \* this formula will stay in place for extended duration of relief \* avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

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

LORNAMEAD  
 1.000 X 1.000 X 4.313 - PRINTSIDE  
 SBS S170271 - 3/9/17



LORNAMEAD, INC.		PROJECT INFO   PRODUCTION NOTES	
DATE:	APRIL 27, 2020		
PROJECT:	RITE AID 4X MEDICATED TOOTHACHE CREAM CARTON		
ITEM #:	2821614R1		
DIELINE #:	S170271		
SIZE:	1.000" X 1.000" X 4.313"		
FILE NAME:	RA_4XMEDICATED_TOOTHACHE_CREAM_CTN_2821614R1-OLAI		
PRINTER:	MODPAC		
NOTE(S):			
		<b>APPROVALS</b> CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____	
<small>NEW YORK OFFICE   1359 BROADWAY   17TH FLOOR   NEW YORK, NY 10018            TONAWANDA OFFICE   175 COOPER AVENUE   TONAWANDA, NEW YORK 14150</small>			

Toothache & gum reliever  
 20% benzocaine to relieve oral pain  
 antiseptic to kill harmful bacteria  
 astringent to help prevent infection  
 menthol to soothe gums  
 4x medicated  
 oral antiseptic/pain reliever/astringent  
 Net Wt 0.33 oz (9.4 g)

## 4X MEDICATED SEVERE TOOTHACHE AND GUM CREAM

benzocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0614
<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>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.26 g in 100 g
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	

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

### Product Characteristics

<b>Color</b>	white	<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:11822-0614-9	1 in 1 CARTON	05/06/2020	
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 not final	part356	05/06/2020	

**Labeler** - Rite Aid (014578892)

**Registrant** - Lornamead (080045418)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(11822-0614)

Revised: 1/2023

Rite Aid