

## **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 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 \* 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 \* adults and children 2 years of age and older; apply a small amount of product to the cavity and around the 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



		<b>PROJECT INFO   PRODUCTION NOTES</b>																			
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-OL-AI PRINTER: MODPAC	<table border="1"> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>CYAN</td> <td>MAGENTA</td> <td>YELLOW</td> <td>BLACK</td> </tr> </table>					CYAN	MAGENTA	YELLOW	BLACK	<table border="1"> <tr> <td colspan="2"><b>APPROVALS</b></td> </tr> <tr> <td>CREATIVE</td> <td>_____</td> </tr> <tr> <td>MARKETING</td> <td>_____</td> </tr> <tr> <td>R&amp;D</td> <td>_____</td> </tr> <tr> <td>QUALITY</td> <td>_____</td> </tr> </table>		<b>APPROVALS</b>		CREATIVE	_____	MARKETING	_____	R&D	_____	QUALITY	_____
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NOTES:

PMS 185	COLD FOIL		
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PURCHASING \_\_\_\_\_  
CEO \_\_\_\_\_

NEW YORK OFFICE | 1359 BROADWAY | 17TH FLOOR | NEW YORK, NY 10018  
TONAWANDA OFFICE | 175 COOPER AVENUE | TONAWANDA, NEW YORK 14150

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>	

**Contains****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)**Establishment**

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

Revised: 5/2020

Rite Aid