

## **3X MEDICATED TOOTHACHE AND GUM 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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#### Active Ingredients Purpose

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 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 in the 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**

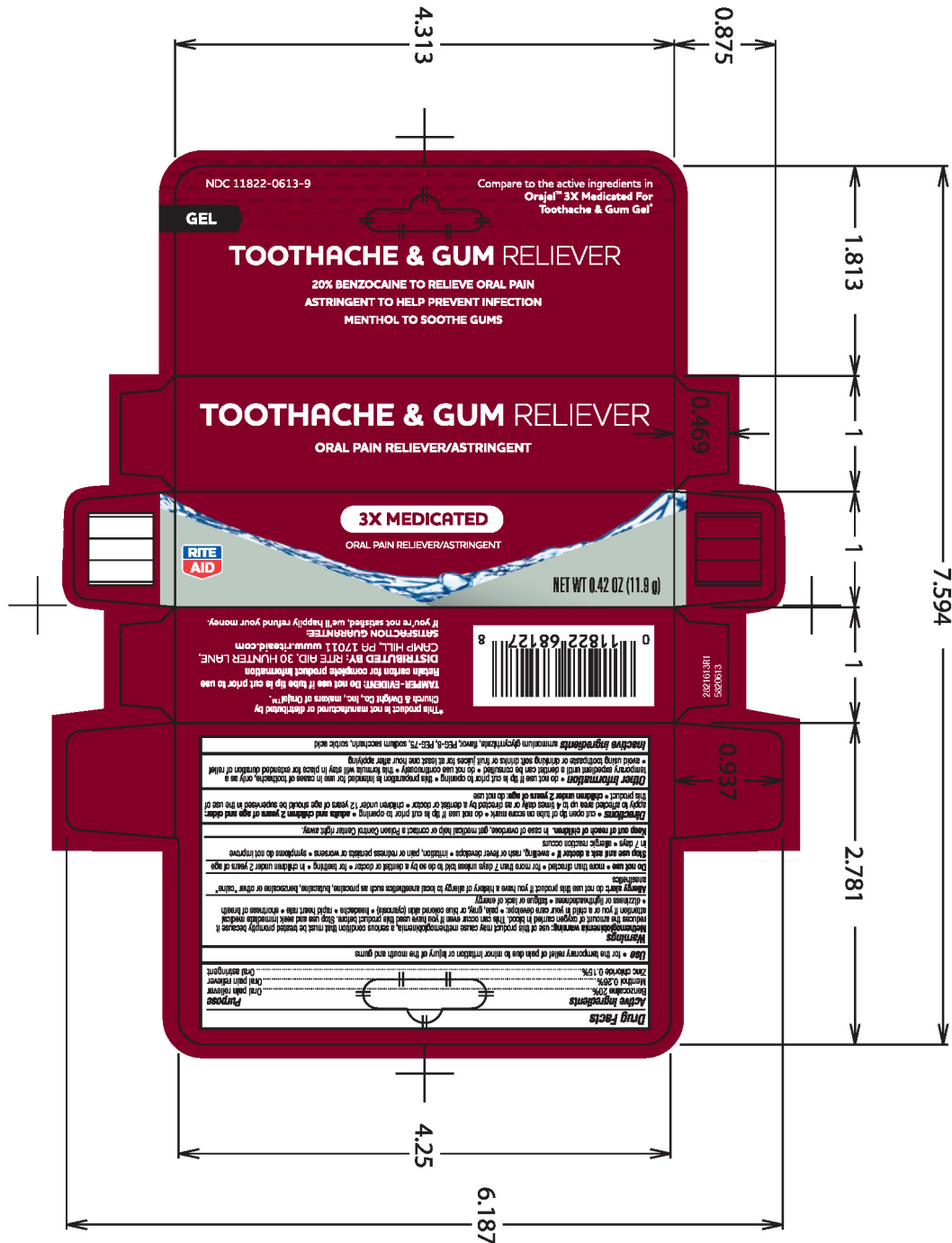
Directions \* cut open tip of tube on score mark \* do not use if tip is cut prior to opening \* adults and children 2 years of age and older: apply to affected area up to 4 times daily or as directed by a dentist or doctor \* children under 12 years of age should be supervised in the use of this product \* children under 2 years of age: do not use

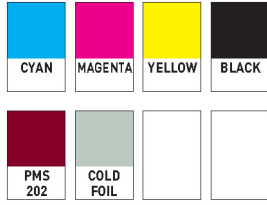
Other information \* do not use if tip is cut prior to opening \* this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted \* do not use continuously ( this formula will stay in place for extended

duration of relief \* avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

Inactive ingredients ammonium glycyrrhizate, favor, PEG-8, PEG-75, sodium saccharin, sorbic acid

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		<b>APPROVALS</b> CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____
PROJECT:	RITE AID 3X MEDICATED TOOTHACHE GEL CARTON		
ITEM #:	2821613R1		
DIELINE #:	S170271		
SIZE:	1.000" X 1.000" X 4.313"		
FILE NAME:	RA_3XMEDICATED_TOOTHACHE_GEL_CTN_2821613R1-OLAJ		
PRINTER:	MODPAC		
NOTE(S):			
<small>NEW YORK OFFICE   1359 BROADWAY   17TH FLOOR   NEW YORK, NY 10019            TONAWANDA OFFICE   175 COOPER AVENUE   TONAWANDA, NEW YORK 14150</small>			

## Toothache and Gum Reliever

20% benzocaine to relive oral pain

Astringent to help prevent infection

Menthol to soothe gums

3x medicated

oral pain reliever/astringent

Net Wt 0.42 oz (11.9 g)

## 3X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0613
<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

### Inactive Ingredients

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

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0613-9	1 in 1 CARTON	05/06/2020	
1		11.7 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(11822-0613)

Revised: 1/2023

Rite Aid