

**4X MEDICATED TOOTHACHE AND GUM CREAM- benzocaine cream  
HEB**

*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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**5820611 4x Med Cream**

Active ingredients Purpose

Benzalkonium chloride 0.13% . . . Oral antiseptic

Benzocaine 20% . . . . . Oral pain reliever

Menthol 0.26% . . . . . Oral pain reliever

Zinc chloride 0.15% . . . . . Oral astringent

**Use**

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

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

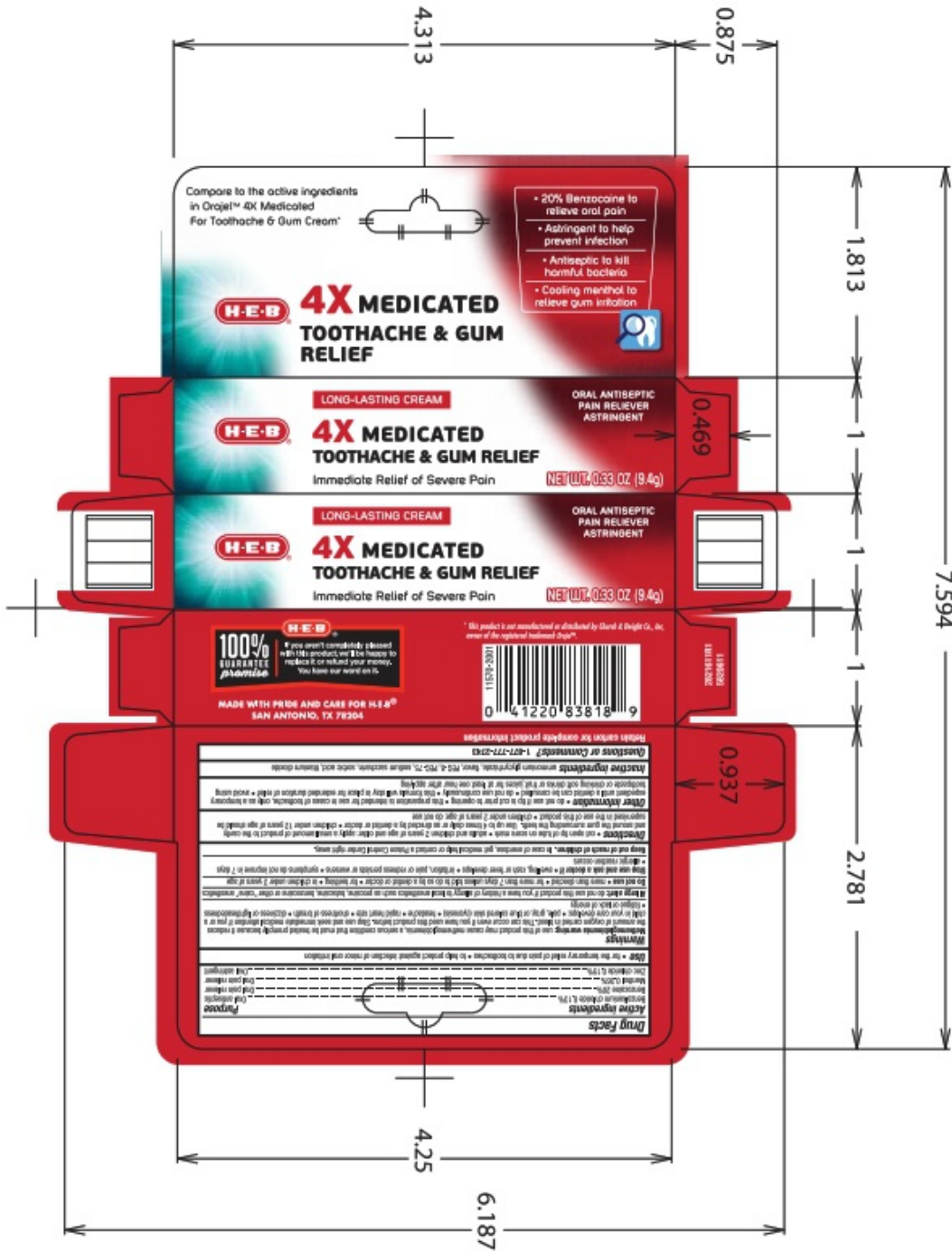
Stop use and ask a doctor if \* swelling, rash or fever develops \* irritation, pain or redness persists or worsens \* symptoms do not improve in 7 days \* allergic reaction occurs

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

Directions \* 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 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

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



		<b>PROJECT INFO   PRODUCTION NOTES</b>																		
DATE: APRIL 22, 2020 PROJECT: HEB 4X MEDICATED TOOTHACHE CREAM CARTON ITEM #: 2821611R1 DELINE #: S170272 SIZE: 1,800" X 1,080" X 4,313" FILE NAME: HEB_4XMEDICATED_TOOTHACHECREAM_CTN_2821611R1-0L-A1 PRINTER: MODPAC NOTE(S):	<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></td> <td></td> <td></td> <td></td> </tr> <tr> <td>WHITE</td> <td>PMS 186</td> <td></td> <td></td> </tr> </table>					WHITE	PMS 186			<b>APPROVALS</b> CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____	
CYAN	MAGENTA	YELLOW	BLACK																	
WHITE	PMS 186																			
NEW YORK OFFICE   1369 BROADWAY   17TH FLOOR   NEW YORK, NY 10018 TONKAWANDA OFFICE   175 COOPER AVENUE   TONKAWANDA, NEW YORK 14158																				

# 4X MEDICATED TOOTHACHE AND GUM CREAM

benzocaine cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37808-116
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
<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	0.25 g in 100 g
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>AMMONIUM GLYCYRRHIZATE</b> (UNII: 3VRD35U26C)	
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	

## Product Characteristics

<b>Color</b>	white (Cloudy)	<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:37808-116-69	1 in 1 CARTON	06/02/2020	
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 mono graph not final	part356	06/02/2020	

**Labeler** - HEB (007924756)

**Registrant** - Lornamead (126440440)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(37808-116)

Revised: 6/2020

HEB