

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

### **CVS**

*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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### **5820601 4x Med Cream**

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 or 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 or 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



LORNAMEAD  
 1.000 X 1.000 X 4.313 - PRINTSIDE  
 S180906 - 11/16/18



PLEASE LEAVE OUR CVS SLUG ON ALL FINAL ART, PRE-PRESS FILES AND CONTRACT PROOFS FOR FINAL APPROVAL

**CYAN**
 **MAGENTA**
 **YELLOW**
 **BLACK**

**CVS CASUAL**
 **PMS 200**
 **WHITE**
 **OFFSET BLACK**

**OFFSET BLACK**
 **WHITE**
 **OFFSET BLACK**
 **WHITE**

FILE NAME: 731613\_CVSHSHealth\_Orxel\_4XMed-ToothacheCream\_CARTON.ai  
 ITEM NUMBER: 731613  
 PRODUCED BY: LORNAMEAD  
 190808125  
 050428369067

PREP PROCESS: OFFSET LITHO  
 DATE: 11/04/19  
 SUBSTRATE: DELBORN  
 MSN

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**Marks.**  
MARKS DESIGN  

01

File created at 10:31

Illustrator CC

RELEASE DATE: 11/15/19 - MSN

**VENDOR RESPONSIBILITIES**

THIS PROOF SHOULD BE USED AS A VISUAL REFERENCE FOR PROCESS COLOR ONLY. This packaging is required to follow the print specifications outlined by the CVS Print Color Management (PCM) program. Packaging is required to be sent to SGS PMS Call for evaluation immediately following packaging mass production. All specification and evaluation information is available on the program website (MARKS.MARKS.COM). Please contact SGS PMS Call for any questions.

**PREPRESS REQUIREMENTS**

MARKS DESIGN PRINTERS: All color bars in the Proof Color section of this document can be printed as a color spot color or simulated using process color ink. These color bars are required to match the published spot color L\*a\*b\* values within the Delta E color bar as outlined on the PCM program website (marksdesign.com). Additionally, a Proof Color Evaluation Patch for every color must be added to the press sheet in accordance with the program website (marksdesign.com).

Vendor is responsible for proper registration per their printing press profile and color calibration. Marks Design cannot be held responsible for any color deviations. SUPPLIER: PMS 200 for colors not in the PMS list. PMS 200 for colors not in the PMS list. PMS 200 for colors not in the PMS list. PMS 200 for colors not in the PMS list. PMS 200 for colors not in the PMS list. PMS 200 for colors not in the PMS list.

**LORNAMEAD, INC.**

DATE: DECEMBER 31, 2019  
 PROJECT: CVS 4X MEDICATED TOOTHACHE CREAM CARTON  
 ITEM #: 2821601R1  
 DELINE #: 5180906  
 SIZE: 1.000" X 1.000" X 4.313"  
 FILE NAME: CVS\_4XMEDICATED\_TOOTHACHECREAM\_CTN\_2821601R1-0L-AJ  
 PRINTER: MOOPAC  
 NOTE(S):

**PROJECT INFO | PRODUCTION NOTES**

**APPROVALS**

CREATIVE: \_\_\_\_\_

MARKETING: \_\_\_\_\_

R&D: \_\_\_\_\_

QUALITY: \_\_\_\_\_

PURCHASING: \_\_\_\_\_

CEO: \_\_\_\_\_

NEW YORK OFFICE | 1209 BROADWAY | 17TH FLOOR | NEW YORK, NY 10018  
 TONAWANDA OFFICE | 175 COOPER AVENUE | TONAWANDA, NEW YORK 14150

# 4X MEDICATED TOOTHACHE AND GUM CREAM

benzocaine cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69842-631
<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>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.26 g in 100 g

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	white (Cloudy 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:69842-631-19	1 in 1 CARTON	06/05/2020	
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	06/05/2020	

**Labeler** - CVS (062312574)

**Registrant** - Lornamead (080046418)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(69842-631)

Revised: 6/2020

CVS