

4X MEDICATED TOOTHACHE AND GUM CREAM- benzocaine cream CVS

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

FILE NAME	ITEM NUMBER	PRINT PROCESS	
731613_CVSHealth_OrajeL4XMed_ToothacheCream_CARTON.ai	731613	OFFSET LITHO	
PROJECT #	VENDOR	PREPARED BY	DATE
190808125	LORNAMEAD	MODPAC	11/04/19
UPC or SCC#	DELIN#	SUBSTRATE	DESIGNER
050428369057	N/A	FOIL BOARD	MSN

CVS pharmacy **CVS** **PHARMACY** **MARKS.** **01** **Illustrator CC** **RELEASE DATE: 11/15/19 - MSN**

Vendor RESPONSIBILITIES

THIS PROOF SHOULD BE USED AS A VISUAL REFERENCE FOR PROCESS COLOR CHECK. This packaging is required to follow the print specifications defined by the CVS Print Color Management (PCM) program. Packaging is required to be sent to SGS PGM Cell for evaluation immediately following packaging tests produced. All specifications and location information is available on the program website (GAMNET.MCGM/CMV). Please contact SGS PGM Cell for any questions.

PREPRESS REQUIREMENTS

DATE/TIME ON PRINTERS NOTE: All colors listed in the Match Colors section of this document can be printed as solid spot color or simulated using process color ink. These colors are NOT required to match to the published spot color PANTONE values within the Global Dimensions as outlined on the PGM program website (GAMNET.MCGM/CMV). Additionally, a Spot Color Simulation Patch for every color must be added to the press sheet to allow for color management. Refer to the published Color Target Guidelines on the PGM program website (GAMNET.MCGM/CMV).

Vendor is responsible for proper separations per their printing press profile including trapping, bleeds and minimum tolerance adjustments. REPLACE ALL WHITE SPACES WITH FOUR SPICES, ENLARGED SPICES AND Supply PDF for content proof review and with its approval supply 2 subsequent contract proofs per project schedule.

LORNAMEAD, INC. **PROJECT INFO | PRODUCTION NOTES**

DATE: DECEMBER 31, 2019
PROJECT: CVS 4X MEDICATED TOOTHACHE CREAM CARTON
ITEM #: 2821601R1
DELIN#: S180906

APPROVALS

CREATIVE: _____
MARKETING: _____

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

SIZE: 1.000" X 1.000" X 4.313"					R&D _____
FILE NAME: CVS_XXMEDICATED_TOOTHACHECREAM_CTN_2821601R1-DLJM					QUALITY _____
PRINTER: MODPAC					PURCHASING _____
NOTE(S):					CEO _____
	WHITE	PMS 200			
NEW YORK OFFICE 130F 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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-631
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.26 g in 100 g

Inactive Ingredients

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

Product Characteristics

Color	white (Cloudy White)	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

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 Drug	M022	06/05/2020	

Labeler - CVS (062312574)

Registrant - Lornamead (080046418)

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

Revised: 1/2025

CVS