

4X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel

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.

5820602 4x Med Gel

Benzalkonium chloride 0.13% . . . Oral antiseptic

Benzocaine 20% . . . Oral pain reliever

Menthol 0.5% . . . 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.

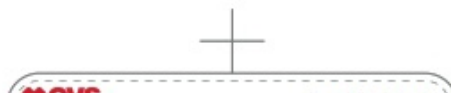
Directions

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 least one hour after applying

ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid



LORNAMEAD
1.031 X 1.031 X 3.500 - PRINTSIDE
FOIL S170274 - 3/9/17



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

CVS pharmacy

CYAN MAGENTA YELLOW BLACK

FILE NAME	933533_CVSHHealth_Orajel_4XMed_ToothacheGel_CARTON.ai	ITEM NUMBER	933533	PRINT PROCESS	OFFSET LITHO
PROJECT #		VENDOR	LORNAMEAD	PRINTER	MODPAC
190808125		DATE	1/10/17	SUBSTRATE	MSN
UPC OR SSC#	050428251041	FOIL BOARD		DESIGNER	

Marks.

01

File created at 100%

Illustrator CC
RELEASE DATE:
11/15/19 - MSN

VENDOR RESPONSIBILITIES

THIS PROOF SHOULD BE USED AS A VISUAL REFERENCE FOR PROGRESS COLOR ONLY. This packaging is required to follow the print specifications outlined by the CVS Print Quality Management (PQM) program. Packaging is required to be sent to 9335 PSM Call for evaluation immediately following packaging media production. All specifications and validation information is available on the program website (PQM.PHARM.COM/CVS). Please contact 933 PSM Call by emailing CVSINFORMATION@933.COM with any questions.

PREPRESS REQUIREMENTS

ATTENTION PROofer: All colors based on the Match Color version of this document can be printed on a solid spot color or simulated using process color. These colors are not required to match the published spot color 1" x 1" values unless the Match Color document is utilized on the PQM program website (PQM.PHARM.COM/MSN). 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 Control Target Guidelines on the PQM program website (PQM.PHARM.COM/MSN). Vendor is responsible for proper registration per their printing press profile including trapping, bleed, and minimum tolerance requirements. PLEASE UPGRADE WITH PROPER BURN PER YOUR SPEC. ENSURE UPC SCANS. Supply PDF for content proof review and with its approval supply 2 enhancement contact priority per program schedule.

LORNAMEAD, INC.				PROJECT INFO PRODUCTION NOTES									
DATE:	DECEMBER 20, 2019												
PROJECT:	CVS 4X MEDICATED TOOTHACHE GEL CARTON												
ITEM #:	2821602R1												
DIELINE #:	5170274												
SIZE:	1031" X 1.031" X 3.500"												
FILE NAME:	CVS_4XMEDICATED_TOOTHACHEGEL_CTN_2821602R1-OL.AI												
PRINTER:	MODPAC												
NOTE(S):													
				<table border="1" style="width: 100%;"> <tr> <td>CYAN</td> <td>MAGENTA</td> <td>YELLOW</td> <td>BLACK</td> </tr> <tr> <td>WHITE</td> <td>PMS 200</td> <td></td> <td></td> </tr> </table>		CYAN	MAGENTA	YELLOW	BLACK	WHITE	PMS 200		
CYAN	MAGENTA	YELLOW	BLACK										
WHITE	PMS 200												
				APPROVALS CREATIVE: _____ MARKETING: _____ R&D: _____ QUALITY: _____ PURCHASING: _____ CEO: _____									

4X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-642
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
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	0.5 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
SORBIC ACID (UNII: X045WJ989B)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Product Characteristics

Color	blue	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-642-29	1 in 1 CARTON	06/05/2020	
1		7.1 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(69842-642)

Revised: 6/2020

CVS