

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

FILE NAME 033533_CVSHealth_Crajel_4XMed_ToothacheGel_CARTON.ai	ITEM NUMBER 033533
PROJECT # 190806125	PRINT PROCESS OFFSET LITHO
VENDOR LORNAMEAD	DATE 11/04/19
UPC or SCCN 050428251041	SUBSTRATE DESIGNED # MSN

Marks.

01

File created at 10:08

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 Quality Management (PQM) program. Packaging is required to be sent to BSS PQM Call for evaluation immediately following packaging mass production. All qualification and evaluation information is available on the program website: BSSPQM.COM/CMV. Please contact BSS PQM Call by emailing CMVFORM@BSSPQM.COM with any questions.

PREPRESS REQUIREMENTS

ALL TECHNICAL PREPRESS NOTES, as outlined in the Marks Color section of this document, can be printed as a solid spot color or simulated using process color ink. These colors are not required to match the published spot color L*a*b* values within the Default tolerances as outlined on the PQM program website: BSSPQM.COM/CMV. Additionally, a Spot Color Remediation Patch for every color must be added to the press sheet to allow for color measurement. Refer to the published Contract Terms Guidelines on the PQM program website.

printed supplier. Please ensure that your graphics supplier prepares the file for printing. Should the supplied artwork be found to be incorrect please contact your representative immediately.

It is your responsibility to ensure and provide additional labeling that complies with the regulations of the Food and Drug Administration (the "FDA"). Upon request and for a fee, Agcico, together with its affiliates, without limitation, will either perform or direct you to certain third parties who will perform FDA compliance review services. By your signature you acknowledge and agree that, notwithstanding any terms, conditions, agreements or instructions to the contrary, Agcico shall have no liability with respect to compliance with FDA regulatory labeling requirements, including in cases where Agcico utilizes the services of a third party.

Marks an Agcico company 28 Cumberland Street, Suite 200 Woonsocket, RI 02895 Contact: daborah.green@makemarka.com T +1 (401) 531-2332 www.agcico.com

Illustrator CC

RELEASE DATE:
11/12/19 - MSN

There is no guarantee of success. Customers are not to use program services (signature, content). Provider is responsible for proper registration per their printing process profile including trapping, bleed and minimum tolerance adjustments. PMS colors are not to be used for registration. Supply PMS for correct print process and with the approval supply of subsequent contract per project schedule.

LORNAMEAD, INC.		PROJECT INFO PRODUCTION NOTES	
DATE: DECEMBER 20, 2019	PROJECT: CVS 4X MEDICATED TOOTHACHE GEL CARTON		APPROVALS CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____
ITEM #: 2821602R1	DIELINE #: S170274		
SIZE: 1031" X 1.031" X 3.500"	FILE NAME: CVS_4XMEDICATED_TOOTHACHEGEL_CTN_2821602R1-0LAI		
PRINTER: MDDPAC	NOTE(S):		
<small>NEW YORK OFFICE 139F BROADWAY 17TH FLOOR NEW YORK, NY 10018 TONAWANDA OFFICE 175 COOPER AVENUE TONAWANDA, NEW YORK 14150</small>			

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
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
SORBIC ACID (UNII: X045VJ989B)	

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: 1/2023

CVS