

3X MEDICATED MOUTH SORE 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.

5820600 3x Med Gel

Benzocaine 20% . . . Oral pain reliever

Menthol 0.1% . . . Oral pain reliever

Zinc chloride 0.15% . . . Oral astringent

Uses

temporarily relieves pain caused by * canker sores * cold sores * fever blisters * minor irritation or injury of the mouth and gums

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

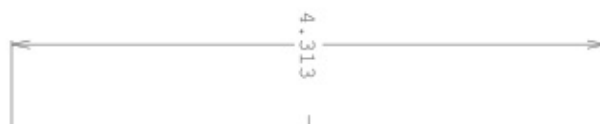
Stop use and ask a doctor if * swelling, rash or fever develops * irritation, pain or redness persists or worsens * symptoms do not improve in 7 days * allergic reaction occurs

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

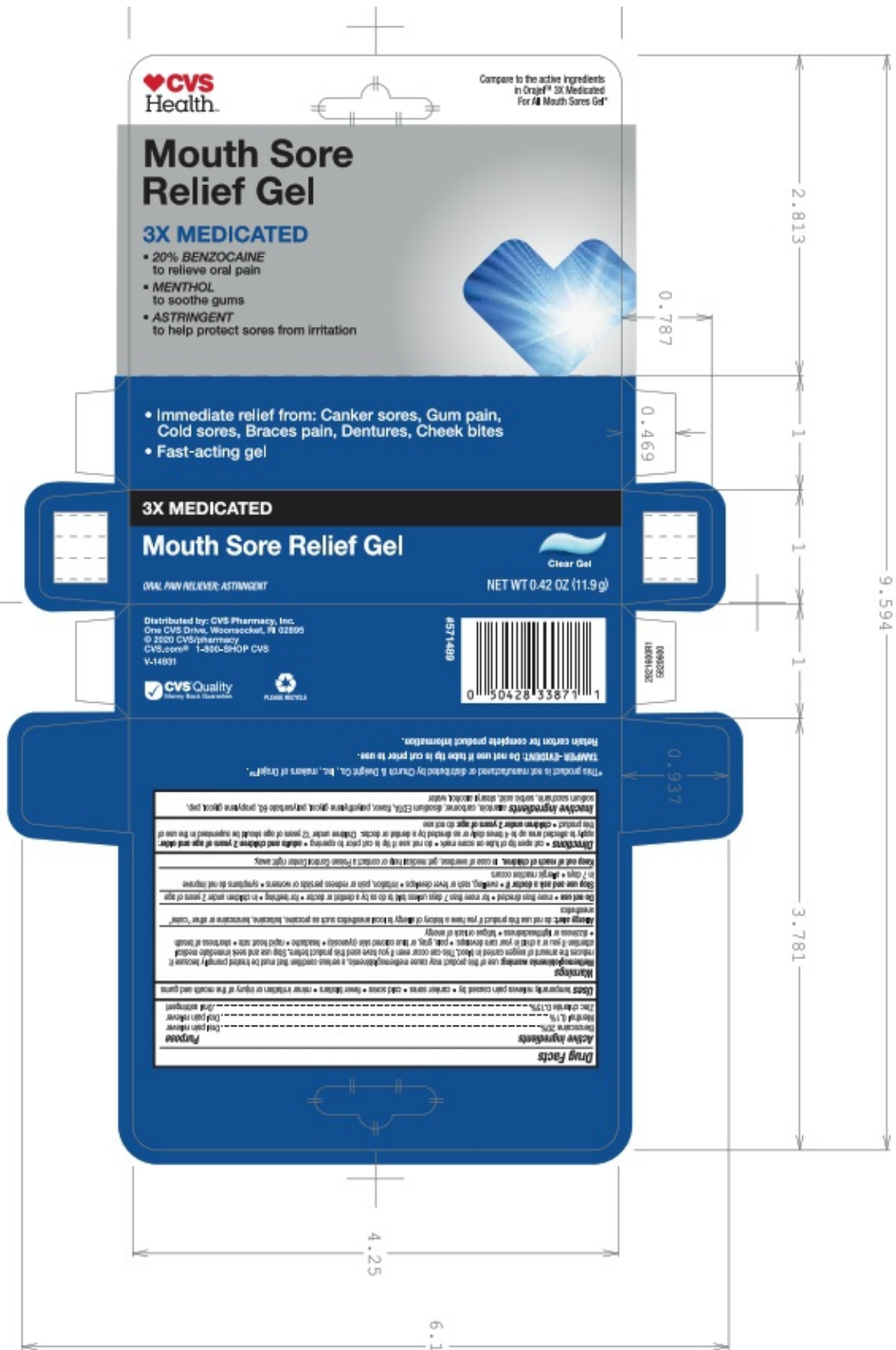
Directions

cut open tip of tube on score mark * do not use if tip is cut prior to opening * adults and children 2 years of age and older: apply to affected area 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

allantoin, carbomer, disodium EDTA, flavor, polyethylene glycol, polysorbate 60, propylene glycol, pvp, sodium saccharin, sorbic acid, stearyl alcohol, water



LORNAMEAD
1.000 X 1.000 X 4.313 - PRINTSIDE
S181083 - 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	
571489_CVSHealth_Orajel_3XMed_MouthSoreGel_CARTON.ai	571489	OFFSET LITHO	
PROJECT #	VENDOR	PRINTER	DATE
190006125	LORNAMEAD	MCDPAC	11/04/19
UPC or SCCP	DIST. INC #	SUBSTRATE	DESI GFIN
050428338711	N/A	PAPERBOARD	MSN

Marks.

01

File created at: 100%

VENDOR RESPONSIBILITIES

THIS PROOF SHOULD BE USED AS A VISUAL REFERENCE FOR PROOF COLOR ONLY. This packaging is required to be proofed and approved by the CVS Print Quality Management (PQM) program. Packaging is required to be sent to SQM PQM Cell for evaluation immediately following packaging mass production. All specification and evaluation information is available on the program website: www.mls.com/cvs. Please contact SQM PQM Cell by emailing: CVSFORMS@MCDPAC.COM with any questions.

PREPRESS REQUIREMENTS

ATTENTION: PREPRESS REQUIREMENTS: All colors listed in the Marked Colors section of this document can be printed as a solid spot color or simulated using process color inks. These colors are all required to match the published spot color library within the ColorCheck tolerance as outlined on the PQM program website (www.mls.com/cvs). Additionally, a Spot Color Simulation Patch for

Signature Graphics Systems/Canada Co. (Sign) and Meta Design has made every effort to comply with CMYK and PMS color and guidelines in the production of this artwork. To the best of our knowledge and experience this artwork adheres to and is compliant with color governing printing requirements as per CMYK color. In the event of an unexplained non-compliance issue that results in printing process approval failure, the printer will be responsible for the cost of any additional materials and labor required to correct the artwork. The printer will not be responsible for the cost of any additional materials and labor required to correct the artwork. The printer will not be responsible for the cost of any additional materials and labor required to correct the artwork.

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

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LORNAMEAD, INC. PROJECT INFO | PRODUCTION NOTES

DATE: DECEMBER 2, 2019
 PROJECT: CVS 3X MEDICATED MOUTHSORE GEL CARTON
 ITEM #: 2821600R1
 DIELINE #: 5181093
 SIZE: 1.000" X 1.000" X 4.313"
 FILE NAME: CVS_3XMEDICATED_MOUTHSOREBEL_CTN_2821600R1-QLAI
 PRINTER: MODPAC
 NOTE(S):

CYAN MAGENTA YELLOW BLACK
 PMS 7686 PMS 10104

APPROVALS
 CREATIVE _____
 MARKETING _____
 R&D _____
 QUALITY _____
 PURCHASING _____
 CEO _____

NEW YORK OFFICE | 1359 BROADWAY | 17TH FLOOR | NEW YORK, NY 10018
 TONAWANDA OFFICE | 175 COOPER AVENUE | TONAWANDA, NEW YORK 14159

3X MEDICATED MOUTH SORE GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-660
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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	0.1 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: B6978945GQ)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
SORBIC ACID (UNII: X045WJ989B)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	

Product Characteristics

Color	yellow (Clear to yellow tint)	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-660-09	1 in 1 CARTON	06/05/2020	
1		11.9 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(69842-660)

Revised: 1/2023

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