3X MEDICATED MOUTH SORE GEL- benzocaine gel
HEB

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.

5820619 3x Med Gel

Active ingredients Purpose

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 methoglobinemia, 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

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

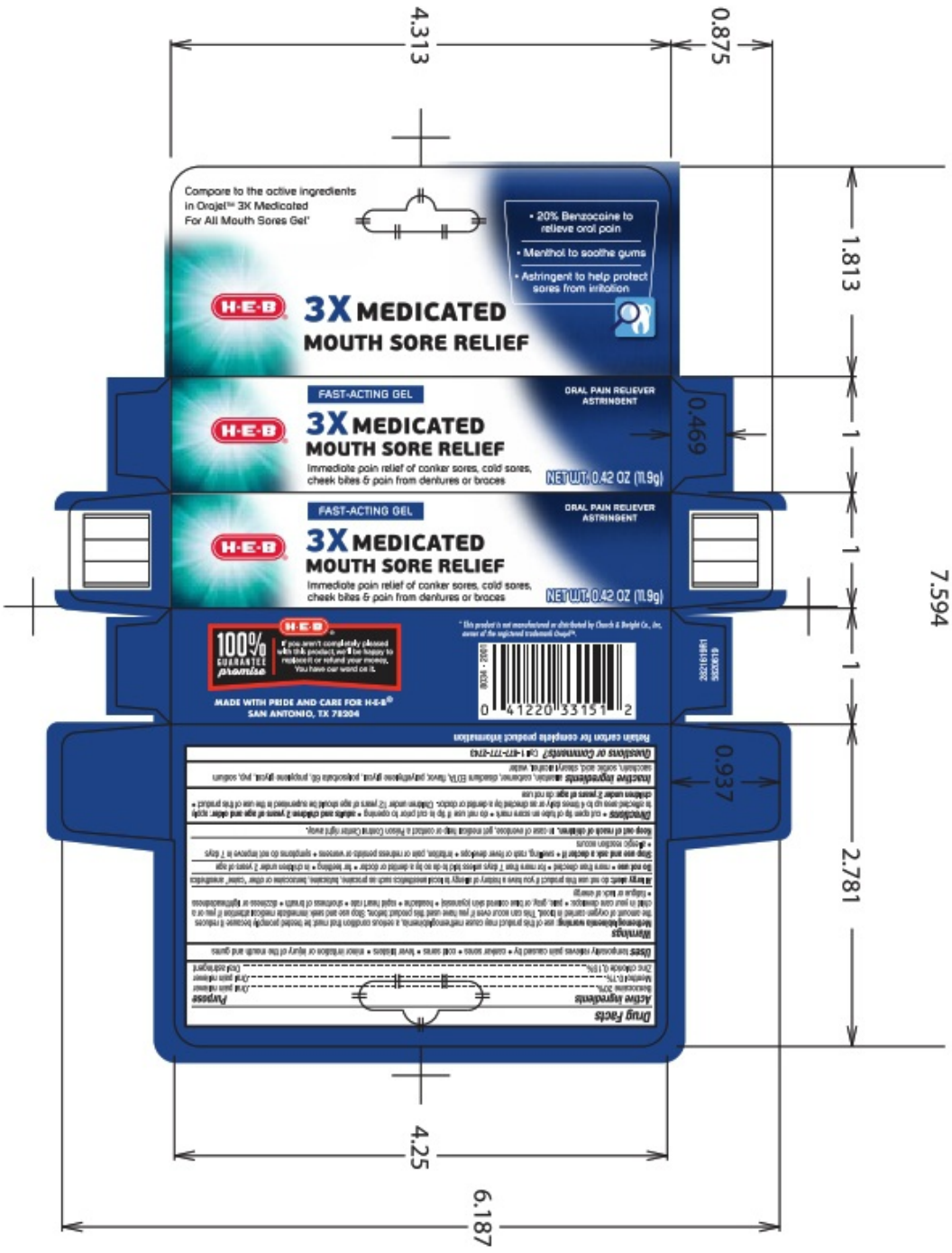
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

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
FOIL S170272 - 3/9/17



LORNAMEAD, INC.

PROJECT INFO | PRODUCTION NOTES

DATE: APRIL 22, 2020
PROJECT: HEB 3X MEDICATED MOUTH SORE GEL CARTON
ITEM #: 2821619R1
DIELINE #: S170272
SIZE: 1.000"X 1.000" X 4.313"
FILE NAME: HEB_3XMEDICATED_MOUTHSOREGEL_CTN_2821619R1-0L.AI
PRINTER: MODPAC
NOTE(S):

CYAN | MAGENTA | YELLOW | BLACK
WHITE | PMS 661

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 14150

3X MEDICATED MOUTH SORE GEL

benzocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-691
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
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
SORBIC ACID (UNII: X045WJ989B)	
ALLANTOIN (UNII: 344S277G0Z)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

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:37808-691-19	1 in 1 CARTON	06/02/2020	
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	06/02/2020	

Labeler - HEB (007924756)

Registrant - Lornamead (126440440)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(37808-691)

Revised: 6/2020 HEB