

4X MEDICATED TOOTHACHE AND GUM CREAM- benzocaine cream 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.

5820611 4x Med Cream

Active ingredients Purpose

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 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

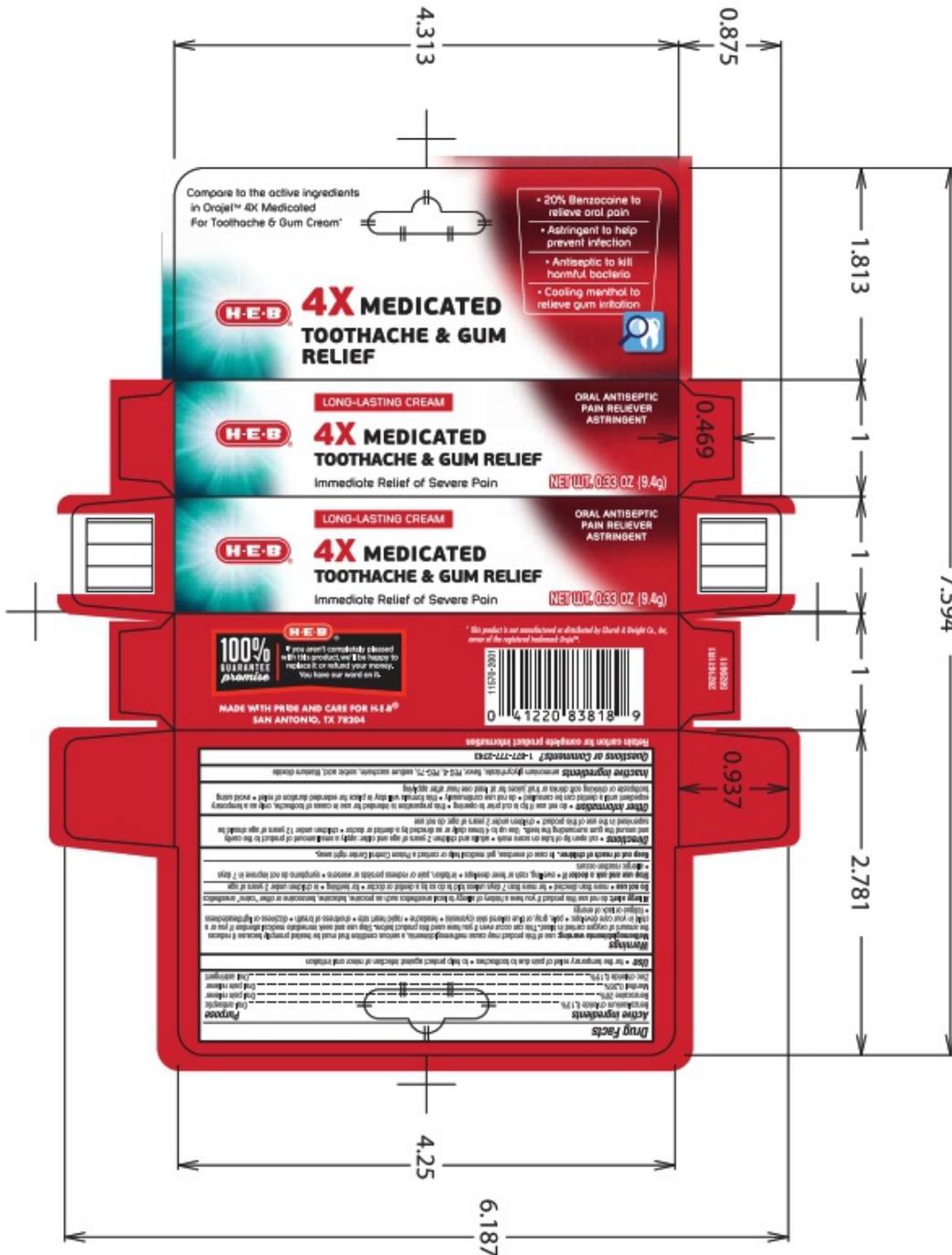
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

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 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
 FOIL S170272 - 3/9/17



DATE: APRIL 22, 2020		APPROVALS CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____
PROJECT: HEB 4X MEDICATED TOOTHACHE CREAM CARTON		
ITEM #: 2821611R1		
DIELINE #: S170272		
SIZE: 1.000" X 1.000" X 4.313"		
FILE NAME: HEB_4XMEDICATED_TOOTHACHECREAM_CTN_2821611R1-0L-A1		
PRINTER: MODPAC	<small>NEW YORK OFFICE 1399 BROADWAY 17TH FLOOR NEW YORK, NY 10018 TONAWANDA OFFICE 175 COOPER AVENUE TONAWANDA, NEW YORK 14152</small>	
NOTE(S):		

4X MEDICATED TOOTHACHE AND GUM CREAM

benzocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-116
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
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
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.25 g in 100 g

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:37808-116-69	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(37808-116)

Revised: 1/2023

HEB