

HEB SEVERE TOOTHACHE AND GUM RELIEF TRIPLE MEDICATED- benzalkonium chloride, benzocaine, menthol 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.

HEB Severe Toothache & Gum Relief Triple Medicated Cream

Drug Facts

Active ingredients

Benzocaine 20%

Menthol 0.25%

Benzalkonium Chloride 0.1%

Purpose

Oral pain reliever

Oral pain reliever

Antiseptic

Use

- for the temporary relief of pain due to toothaches
- to help protect against infection of minor oral irritation

Warnings

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 the 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 between 2 and 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

Inactive ingredients cellulose gum, gelatin, methyl salicylate, mineral oil, pectin, polyethylene glycol, sodium saccharin

MADE WITH PRIDE AND CARE FOR H-E-B®

SAN ANTONIO, TX 78204

H-E-B®

LONG LASTING CREAM

SEVERE TOOTHACHE & GUM RELIEF

ORAL PAIN RELIEVER

ANTISEPTIC

TRIPLE MEDICATED

- 20% Benzocaine for toothache pain relief
- Antiseptic to help prevent infection
- Soothing Menthol for gums

NET WT 0.33 OZ (9.3 g)



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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-313
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
MENTHOL (UNII: 17T10E1B2A) (MENTHOL - UNII: 17T10E1B2A)	MENTHOL	0.25 g

MENTHOL (UNII: L7110E1F3A) (MENTHOL - UNII: L7110E1F3A)		MENTHOL	in 100 g	
Inactive Ingredients				
Ingredient Name				Strength
GELATIN (UNII: 2G86QN327L)				
METHYL SALICYLATE (UNII: LAV5U5022Y)				
MINERAL OIL (UNII: T5L8T28FGP)				
PETROLATUM (UNII: 4T6H12BN9U)				
PECTIN (UNII: 89NA02M4RX)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor	WINTERGREEN	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-313-49	1 in 1 CARTON	02/20/2019	
1		9.3 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	02/20/2019		

Labeler - HEB (007924756)

Registrant - Lornamead Inc. (080046418)

Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(37808-313)