

HEB MOUTH SORE RELIEF- benzalkonium chloride, benzocaine, zinc chloride 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.

HEB Mouth Sore Relief Triple Med Gel

Drug Facts

Active ingredient

Benzalkonium chloride 0.02%

Benzocaine 20%

Zinc chloride 0.1%

Purpose

Oral Antiseptic

Oral Pain Reliever

Oral Astringent

Uses

temporarily relieves of pain caused by:

- canker sores
- cold sores
- fever blisters
- minor irritation of the mouth and gums
- to help protect against infection in 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 the 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, fever develops
- irritation, pain or redness persist or worsen
- sore mouth 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 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

Inactive ingredients Allantoin, Carbomer, Edetate Disodium, Mentha Piperata (Peppermint Oil), Polyethylene Glycol, Polysorbate 60, Propylene Glycol, Propyl Gallate, Purified Water, PVP, Sodium Saccharin, Sorbic Acid, Stearyl Alcohol.

Questions or Comments? Call **1-877-777-2473**

MADE WITH PRIDE AND CARE FOR H-E-B®

SAN ANTONIO, TX 78204

H-E-B

MOUTH SORE RELIEF

FAST-ACTING GEL

TRIPLE MEDICATED

ORAL PAIN RELIEVER/ANTISEPTIC/ASTRINGENT

NET WT 0.42 OZ (11.9 g)

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.02 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALLANTOIN (UNII: 344S277G0Z)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	white (white/clear to yellow to slight pink/orange)	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-312-29	1 in 1 CARTON	02/19/2019	
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	02/19/2019	

Labeler - HEB (007924756)

Registrant - Lornamead Inc. (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(37808-312)

Revised: 1/2023

HEB