

**CVS PHARMACY MOUTH SORE GEL- benzocaine, benzalkonium chloride and zinc chloride gel, dentifrice**

**CVS Pharmacy**

*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.*

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**Drug Facts**

**Active ingredients**

Benzalkonium Chloride 0.02% ..... Oral Antiseptic  
Benzocaine 20.0% (w/w) ..... Oral Pain Reliever  
Zinc Chloride 0.1% ..... Oral Astringent

**Uses**

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

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 directed by a dentist or doctor.
- **Stop use and ask a doctor if** sore mouth symptoms do not improve in 7 days, swelling, rash or fever develops, irritation, pain or redness persists or worsens

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 scoremark
- Adults and children 2 years of age and older: apply a small amount of product to the cavity and around the 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: ask a dentist or doctor.

**Other Information**

Store in a cool dry place. Keep tube capped when not in use.

**Inactive ingredients**

allantoin, carbomer, edetate disodium, mentha piperita, polyethylene glycol, polysorbate 60, propylene glycol, propyl gallate, water, PVP, sodium saccharin, sorbic acid, stearyl alcohol

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mm1.jpg



Compare to the active ingredients in Orajel® Mouth Sore Medicine\*

**NEW!**

# IMMEDIATE MOUTH SORE RELIEF



- Canker sores
- Cold sores
- Gum pain
- Denture pain
- Brace pain
- Cheek bites

TAMPER-EVIDENT: Do not use if tube tip is cut prior to use.



**Maximum Strength**  
**MOUTH SORE GEL**  
**IMMEDIATE PAIN RELIEF**  
 Triple medicated



**Maximum Strength**  
**MOUTH SORE GEL**  
**IMMEDIATE PAIN RELIEF**



**Maximum Strength**  
**MOUTH SORE GEL**  
**IMMEDIATE PAIN RELIEF**  
 Triple medicated

Compare to the active ingredients in Orajel® Mouth Sore Medicine\*



**Maximum Strength**  
**MOUTH SORE GEL**  
**IMMEDIATE PAIN RELIEF**

NET WT 0.42 OZ (11.9g)

# 851676



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**Drug Facts**

**Active ingredients**  
 Benzalkonium Chloride 0.02%  
 Benzocaine 20%  
 Zinc Chloride 0.1%  
 Oral Antiseptic  
 Oral Pain Reliever  
 Oral Astringent

**Purpose**

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

**Warnings**  
 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

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

**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: ask a dentist or doctor

**Inactive ingredients** Menthol, Carbomer, Edetate Disodium, Mentha Piperita (Peppermint) Oil, Polyethylene Glycol, Polysorbate 60, Propylene Glycol, Purified Water, PVP, Sodium Pivalate, Sorbic Acid, Stearyl Alcohol



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Orajel® Mouth Sore Medicine\*

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**MOUTH SORE GEL**  
**IMMEDIATE PAIN RELIEF**

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**Active ingredient:** Benzalkonium Chloride 0.02%, Benzocaine 20%, Zinc Chloride 0.1% **Use:** temporarily relieves pain caused by canker sores, cold sores, fever blisters, minor irritation or injury of the mouth and gums **Warnings:** **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. **Stop use and ask a doctor if** • sore mouth symptoms do not improve in 7 days • swelling, rash or fever develops • irritation, pain, or redness persists or worsens . **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:** ask a dentist or doctor

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### CVS PHARMACY MOUTH SORE GEL

benzocaine gel, dentifrice

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:59779-913
<b>Route of Administration</b>	Oral	<b>DEA Schedule</b>	

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (BENZOCAINE)	BENZOCAINE	20.00 g in 100 g
BENZALKONIUM CHLORIDE (BENZALKONIUM)	BENZALKONIUM CHLORIDE	0.02 g in 100 g
ZINC CHLORIDE (ZINC CATION)	ZINC CHLORIDE	0.1 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400	
POLYSORBATE 60	
WATER	
SACCHARIN SODIUM	
EDETATE DISODIUM	

SORBIC ACID
STEARYL ALCOHOL
POVIDONE K90
CARBOMER HOMOPOLYMER TYPE B
PROPYLENE GLYCOL
ALLANTOIN
PROPYL GALLATE

### Product Characteristics

<b>Color</b>	white (White clear to slight pink orange)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PEPPERMINT (mentha piperota)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-913-99	1 in 1 CARTON		
1	NDC:59779-913-92	11.9 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	10/01/2012	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Lornamead (126440440)

### Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(59779-913), pack(59779-913)