

## **RITE AID MAXIMUM STRENGTH- benzocaine gel, dentifrice**

### **Rite Aid**

*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 ingredient**

Benzalkonium Chloride 0.02% ..... Oral Antiseptic  
Benzocaine 7.5% ..... Oral Pain Reliever  
Zinc Chloride 0.1% ..... Oral Astringent

#### **Uses**

temporarily 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 told to do so by a dentist or doctor.
- Stop use and ask a doctor if sore mouth symptoms do not get better 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 doctor. Children under 12 years should be supervised in the use of this product.

**Children under 2 years of age:** ask a dentist or doctor

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#### **Other Information**

Do not use if tip is cut prior to opening.

#### **Inactive ingredients**

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

mml.jpg



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

# MAXIMUM STRENGTH anesthetic gel mouth sore relief

immediate pain relief  
triple medicated

benzocaine 20%

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

# anesthetic gel mouth sore relief

benzocaine 20%

2621317R1  
5820317

immediate relief of:  
canker sores, cold sores, gum sores,  
cheek bites, brace pain, denture  
irritation, dental work

# MAXIMUM STRENGTH anesthetic gel mouth sore relief

benzocaine 20%

NET WT 0.42 OZ (11.9 g)

DISTRIBUTED BY:  
RITE AID, 30 HUNTER LANE  
CAMP HILL, PA 17011  
MADE IN USA



IF YOU'RE NOT  
SATISFIED, WE'LL  
HAPPILY REFUND  
YOUR MONEY.

\*This product is not manufactured or distributed by Church & Dwight Co., Inc., owner of the registered trademark Orajel®.

STRIP IN UPC:  
0=11822-61044  
85% MAGNIFICATION,  
20% TRUNCATION,  
DOTTED RULE DOES  
NOT PRINT.

ITEM 331044

**Drug Facts**

**Active ingredient**  
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

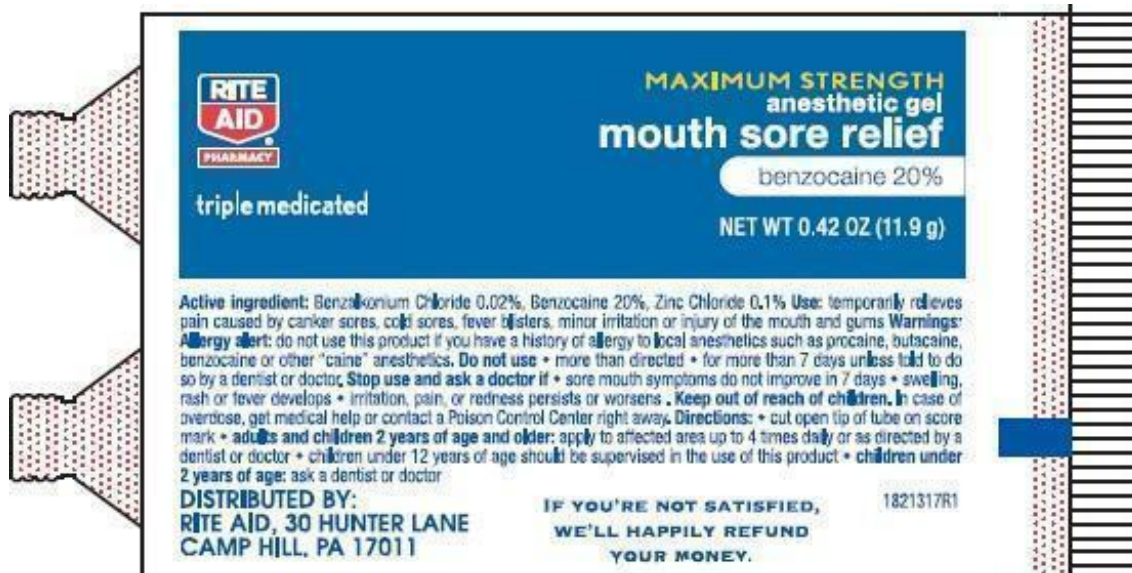
**Warnings**  
**Allergy alert:** do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine,  
benzocaine or other "caine" anesthetics

**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

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



## RITE AID MAXIMUM STRENGTH

benzocaine gel, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0317
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZO CAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20.0 g in 100 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.04 g in 100 g
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC	0.1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYETHYLENE GLYCOLS</b> (UNII: 3WJQ0SDW1A)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: HHT01ZNK31)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL GALLATE</b> (UNII: 8D4SNN7V92)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	

## Product Characteristics

<b>Color</b>	white (White / Clear to slight pinkish orange)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	PEPPERMINT (Peppermint)	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0317-9	1 in 1 CARTON		
1	NDC:11822-0317-2	11.9 g in 1 TUBE		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/20/2011	

**Labeler** - Rite Aid (014578892)

**Registrant** - Lornamead (126440440)

## Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		126440440	manufacture(11822-0317) , pack(11822-0317)

Revised: 1/2013

Rite Aid