

## **LEADER ORAL PAIN RELIEF ANESTHETIC- benzocaine 20% gel**

### **Cardinal Health**

*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**

Benzocaine, 20%

#### **Purpose**

Oral pain reliever

#### **Uses**

For the temporary relief of minor toothache, pain and sore mouth associated with canker sores, dentures and orthodontic appliances.

#### **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 directed by a dentist or doctor.

#### *Stop use and ask a Doctor if:*

- swelling, rash, or fever develops
- irritation, pain or redness persists or gets worse

*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.

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 the product.

Children under 2 years of age, consult a doctor.

#### **Other Information**

- Do not use if tube tip is cut prior to opening.
- Store at room temperature.

**Inactive Ingredients**

Flavors, PEG 4, PEG 540, PEG 75, PEG 8, Sodium Saccharin, Sorbic Acid.

*Maximum Strength*

**Oral Pain Relief**

Anesthetic Gel

ORAL PAIN RELIVER

BENZOCAINE 20%

0.5OZ (14.2G)

carton image

110\*54\*22mm

NDC 37205-607-05

Compare to  
**Orajel®**  
active ingredient\*

**LEADER®**

Maximum Strength

# Oral Pain Relief

**Anesthetic Gel**

Benzocaine 20%



Instant relief of toothache pain.

**LEADER®**

Maximum Strength

# Oral Pain Relief

**Anesthetic Gel**

Benzocaine 20%

0.5 OZ (14.2 g)



Compare to  
**Orajel®**  
active ingredient\*

**LEADER®**  
Maximum Strength  
**Oral Pain Relief**  
Anesthetic Gel

DISTRIBUTED BY:  
CARDINAL HEALTH  
Dublin, Ohio 43017 USA  
CIN 4208419  
1-800-200-6313  
www.myleader.com

All Leader Brand products are 100% satisfaction guaranteed or return to place of purchase for a full refund.

Cat. No. 0443-000 1504430  
Made in USA Rev. 7/09



\*This product is not manufactured or distributed by Del Pharmaceuticals, Inc., a subsidiary of Del Laboratories, Inc., owners of the registered trademark Orajel®.

<b>Drug Facts</b>	<b>Active ingredient:</b> Benzocaine, 20%
<b>Uses</b> For the temporary relief of minor toothache, pain and sore mouth associated with canker sores, dentures and orthodontic appliances.	<b>Purpose:</b> Oral pain reliever
<b>Warnings</b> <b>Allergy Alert:</b> do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics.	
<b>Do Not Use:</b> - more than directed - for more than 7 days unless directed by a dentist or doctor.	
<b>Stop Use and Ask a Doctor If:</b> - swelling, rash, or fever develops - irritation, pain or redness persists or gets worse.	
<b>Keep Out of Reach of Children:</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> - Cut open tip of tube. 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 the product.	Consult a doctor.
Children under 2 years of age Do not use if tube tip is cut prior to opening. - Store at room temperature.	
<b>Inactive ingredients</b> Flavors, PEG 4, PEG 540, PEG 75, PEG 8, Sodium Saccharin, Sorbic Acid.	

**LEADER®**  
Maximum Strength  
**Oral Pain Relief**  
Anesthetic Gel



Maximum Strength

Oral Pain Relief

Anesthetic Gel

ORAL PAIN RELIVER

BENZOCAINE 20%

0.5OZ (14.2G)

tube image

58.6mm

13mm

5mm

**NDC 37205-607-05**

**LEADER**<sup>®</sup>  
Maximum Strength

# Oral Pain Relief

**Anesthetic Gel**

**Benzocaine 20%**

**0.5 OZ (14.2 g)**

Compare to Orajel<sup>®</sup> active ingredient\*

**SATISFACTION GUARANTEE**

**INDICATIONS:** For prompt toothache pain relief and for the temporary relief of pain associated with canker sores, minor dental procedures or minor irritation of the mouth and gums caused by dentures or orthodontic appliances.

**DIRECTIONS:** Cut open tube tip on the score mark. Adults and children 2 years of age and older: Apply to the affected area directly from tube tip or with fingertip. Use up to 4 times daily or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of the product. Children under 2 years of age: Consult a dentist or physician.

**WARNINGS:** Do not use this product for more than 7 days unless directed by a dentist or physician. If sore mouth symptoms do not improve in 7 days; if irritation, pain or redness persists or worsens; or if swelling, rash or fever develops, see your dentist or physician

Keep this and all medication out of reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Store at controlled room temperature 59° - 86°F (15° - 30°C).

**Active Ingredient:** Benzocaine 20%

**Inactive Ingredients:** Flavor, PEG 4, PEG 540, PEG 75, PEG 8, Sodium Saccharin, Sorbic Acid.

**DISTRIBUTED BY:** CARDINAL HEALTH  
Dublin, Ohio 43017 USA  
CIN 4208419  
1-800-200-6313  
www.myleader.com

1304430 Rev. 7/09

83mm



## LEADER ORAL PAIN RELIEF ANESTHETIC

benzocaine 20% gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37205-607
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzocaine</b> (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	200 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SACCHARIN SODIUM DIHYDRATE</b> (UNII: SB8ZUX40TY)	
<b>Sorbic Acid</b> (UNII: X045WJ989B)	
<b>POLYETHYLENE GLYCOLS</b> (UNII: 3WJQ0SDW1A)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-607-06	1 in 1 CARTON		
1	NDC:37205-607-05	14.2 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part356	08/08/2012	

**Labeler** - Cardinal Health (097537435)

**Registrant - Lee Pharmaceuticals (056425432)****Establishment**

Name	Address	ID/FEI	Business Operations
Cardinal Health		097537435	label(37205-607)

**Establishment**

Name	Address	ID/FEI	Business Operations
Lee Pharmaceuticals		056425432	pack(37205-607)

**Establishment**

Name	Address	ID/FEI	Business Operations
Unipack		009248480	manufacture(37205-607)

Revised: 8/2012

Cardinal Health