

LEADER ORAL ANALGESIC- benzocaine 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.

Active ingredient

Purpose

Benzocaine 20%.....Oral Pain Reliever

Uses

- temporarily relieves pain due to toothache, canker sores, cold sores, fever blisters, minor irritation of the mouth and gums cause by dentures or orthodontic appliances

Warnings

Allergy alert: do not use this product if you have a history of allergic 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 doctor/dentist

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

Keep out of reach of children.

In case of overdose or allergic reaction, get medical help or contact a Poison Control Center right away

Directions

- remove cap and cut tip of tube on score mark
- adults and children 2 years of age and older: apply a small amount of Oral Analgesic Gel to the cavity and around gum surrounding the teeth. Use up to 4 times daily or as directed by a doctor or dentist
- children under 12 years of age: should be supervised when using this product
- children under 2 years of age: ask a doctor/dentist

Other information

- store at 15° to 25°C (59° to 77°F)
- do not use if tube tip is cut prior to opening
- this preparation is intended for use in cases of toothaches, only as a temporary expedient until a dentist can be consulted
- do not use continuously
- Lot no and Exp. Date: see box or see crimp of tube

Inactive ingredients

d-sorbitol solution, flavor, glycerin, polyethylene glycol 400, polyethylene glycol 4000, saccharin sodium hydrate

DISTRIBUTED BY CARDINAL HEALTH

DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

Made in Korea



Compare to
Orajel®

MAXIMUM STRENGTH
Oral Analgesic Gel
Benzocaine 20%

Provides IMMEDIATE Relief from:
• Toothache • Denture and Gum Irritations • Cold and Canker Sores



MAXIMUM STRENGTH
Oral Analgesic Gel
Benzocaine 20%



NET WT. 0.42 oz (11.9g)



Made in Korea

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

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DUBLIN, OHIO 43017
CIN 4527156
www.myleader.com
1-800-200-6313

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

Drug Facts
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Questions or comments? 1-800-814-8028

LOT & EXP.

LEADER ORAL ANALGESIC
benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37205-122
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYETHYLENE GLYCOL 4000 (UNII: 4R4HFI6D95)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37205-122-12	1 in 1 CARTON	10/11/2016	
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 final	part333B	05/01/2012	

Labeler - CARDINAL HEALTH (097537435)

Revised: 7/2017

CARDINAL HEALTH