

ZILACTIN-B- benzocaine gel
Blairex Laboratories, Inc.

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.

Drug Facts

Active ingredient

Benzocaine 10%

Purpose

Oral pain reliever

Use

temporarily relieves pain caused by:

- canker sores
- minor mouth sores and gum irritations
- denture and brace pain

Warnings

Flammable:

- keep away from fire or flame

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

Stop use and ask a physician if

- sore mouth symptoms do not improve in 7 days
- swelling, rash or fever develops
- irritation, pain or redness persists or worsens
- apply only to affected area
- do not exceed recommended dosage
- avoid contact with the eyes
- do not use for more than 7 days unless directed by a physician or dentist

Keep out of reach of children. If swallowed, get medical help or contact a poison control center immediately.

Directions

adults and children 2 years and older	Dry affected area. Apply a thin coat of gel with cotton swab or clean finger up to 4 times daily. Allow to dry 30-60 seconds.
children under 12 years	adult supervision should be given in the use of this product
children under 2 years	do not use, consult a physician or dentist

Other information

- do not peel off protective film. Attempting to peel off film may result in skin irritation or tenderness. To remove film, first apply another coat of Zilactin-B Long Lasting Mouth Sore Gel to film, and immediately wipe the area with a moist gauze pad or tissue.
- contains alcohol 65% by volume
- store at 15-30°C (59-86°F)

Inactive ingredients

Boric acid, hydroxypropylcellulose, propylene glycol, purified water, salicylic acid, SD alcohol 38-B, tannic acid

Manufactured for: Blairex Laboratories, Inc. P.O. Box 2127 Columbus, IN 47202 USA

 Questions or Comments?

Call TOLL FREE 1-800-252-4739

www.zilactin.com

PROMOTES HEALING

Oral Pain Reliever

Zilactin[®]-B 6 Hour Canker & Mouth Sore Relief

- Bioadhesive Promotes Healing
- Eat and Drink Pain-Free for up to 6 Hours

Net wt. 0.25 oz (7g)

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Relieves Pain Caused by
Canker Sores, Dentures or Braces

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zilactin-B®

Long Lasting Mouth Sore Gel



000-500028-04



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Blair Laboratories, Inc.
P.O. Box 2127 Columbus, IN 47202 USA
Questions or Comments?
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Tamper Evident Feature: Do not use if glued carton has been opened or tampered with.

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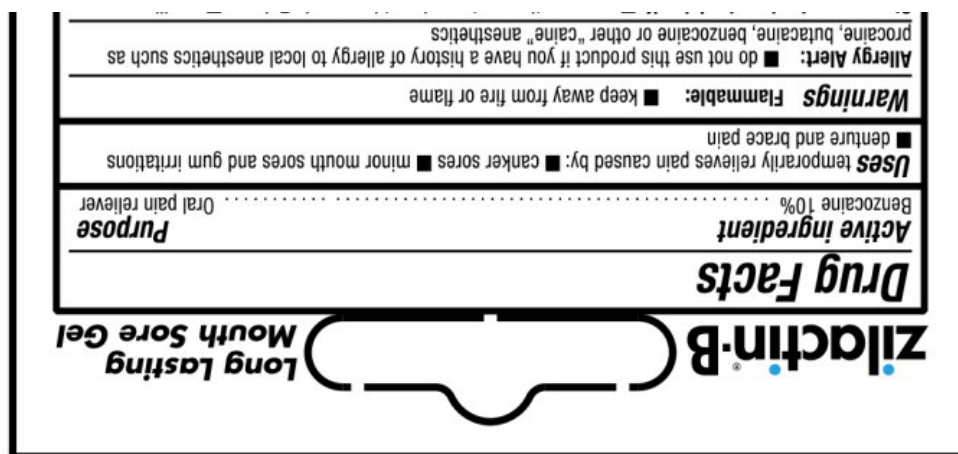
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rash or fever develops ■ irritation, pain or redness persists or worsens



ZILACTIN-B

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50486-550
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	0.1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
HYDROXYPROPYL CELLULOSE (TYPE M) (UNII: U3JF91U133)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ALCOHOL (UNII: 3K9958V90M)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TANNIC ACID (UNII: 28F9E0DJY6)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50486-550-32	1 in 1 CARTON	06/29/2005	
1		7 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	06/29/2005	

Labeler - Blairex Laboratories, Inc. (092575133)

Revised: 11/2021

Blairex Laboratories, Inc.