

BACTIMICINA FOR SORE THROAT- benzocaine lozenge
DLC 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.

Bactimicina Lozenge

Drug Fact

Active Ingredient (in each lozenge)

Benzocaine 15 mg

Purpose

Oral anesthetic/Analgesic

Use

temporarily relieve:

- occasional minor irritation, pain, sore mouth and sore throat

Warnings

Methemoglobinemia warning:

Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- shortness of breath
- headache
- dizziness or lightheadedness
- rapid heart rate
- fatigue or lack of energy

Allergy Alert

Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or any other "caine" anesthetics. If skin reaction occurs, stop use and seek medical help right away.

Sore throat warning:

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly.

Do not use

- for teething
- in children under 5 years of age

When using this product

- do not exceed recommended dosage

Stop use and ask a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

If pregnant or breast-feeding

ask a health professional before use

Keep out of reach of children

In case of overdose, or if more than used for pain relief is accidentally swallowed, get medical help or contact a Poison Control Center immediately

Directions

- **adults and children 5 years of age and older:**

Dissolve 1 lozenge slowly in the mouth. May be repeated every 2 hours as needed or as directed by a doctor or dentist.

- **children under 5 years of age:** do not use.

Other information

- protect from moisture
- store at room temperature
- check expiration date before using

Inactive Ingredients

dextrose, FD&C yellow #6, FD&C red #40, corn syrup, hydrogenated cottonseed oil, natural and artificial flavor, propylene glycol, sucrose

Question

1-800-858-3889

Distributed by

De La Cruz Products

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24286-1577
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	
HYDROGENATED COTTONSEED OIL (UNII: Z82Y2C65EA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
DEXTROSE (UNII: IY9XDZ35W2)	
CORN SYRUP (UNII: 9G5L16BK6N)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	20mm
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24286-1577-1	3 in 1 BOX	12/21/2021	
1		6 in 1 BLISTER PACK; 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	12/21/2021	

Labeler - DLC Laboratories, Inc. (093351930)