

# **HONEY LEMON SORE THROAT LOZENGES- benzocaine lozenge**

## **CVS Pharmacy**

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**Benzocaine 15 mg**  
**Menthol 2.6 mg**

Active ingredients (in each lozenge)

Benzocaine 15 mg

Menthol 2.6 mg

Purpose

Oral anesthetic

Oral anesthetic

Uses temporarily relieves these symptoms:

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 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)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

**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. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persists or worsens, see your dentist or doctor promptly.

**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**

- for teething
- in children under 2 years of age

Stop use and ask doctor if

sore throat is severe or irritation, pain or redness persists or worsens

sore mouth symptoms do not improve in 7 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact Poison Control Center right away.

### Directions

adults and children 5 years and older - allow 1 lozenge to dissolve slowly in mouth. May be repeated every 2 hours as necessary or as directed by a doctor.

children under 5 years - do not use

### Other information

- store at room temperature
- protect from moisture
- **Contains FD&C yellow No. 5 (tartrazine) as a color additive**

Inactive ingredients: Corn starch, FD&C yellow no. 5 (tartrazine), glucose syrup, glycerin, honey, medium chain triglycerides, natural and artificial flavors, propylene glycol, soybean oil, sucrose and water.

Questions? Call 1-800-245-2898, Monday - Friday, 9AM to 4PM EST



**PROOFING CHECK LIST**

- Color Placement  I approve & proceed with order  X
- Copy (Spelling, Font)  Please make change & reproof
- Barcode  Please review proofing checklist before signing and mailing.
- Proof / Revision level
- Graphics

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tfox

# HONEY LEMON SORE THROAT LOZENGES

benzocaine lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-644
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	2.6 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	17mm
<b>Flavor</b>	LEMON (Honey and Lemon)	<b>Imprint Code</b>	B
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:59779-644-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/18/2015	



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/18/2015	

**Labeler** - CVS Pharmacy (062312574)

**Registrant** - Bestco Inc. (002149136)

### Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(59779-644)