

CHERRY THROAT RELIEF LOZENGES- benzocaine lozenge

Zee Medical

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.

Benzocaine 15 mg

Menthol 3.6 mg

Active ingredient (in each lozenge)

Benzocaine 15 mg

Menthol 3.6 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 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)
- 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.

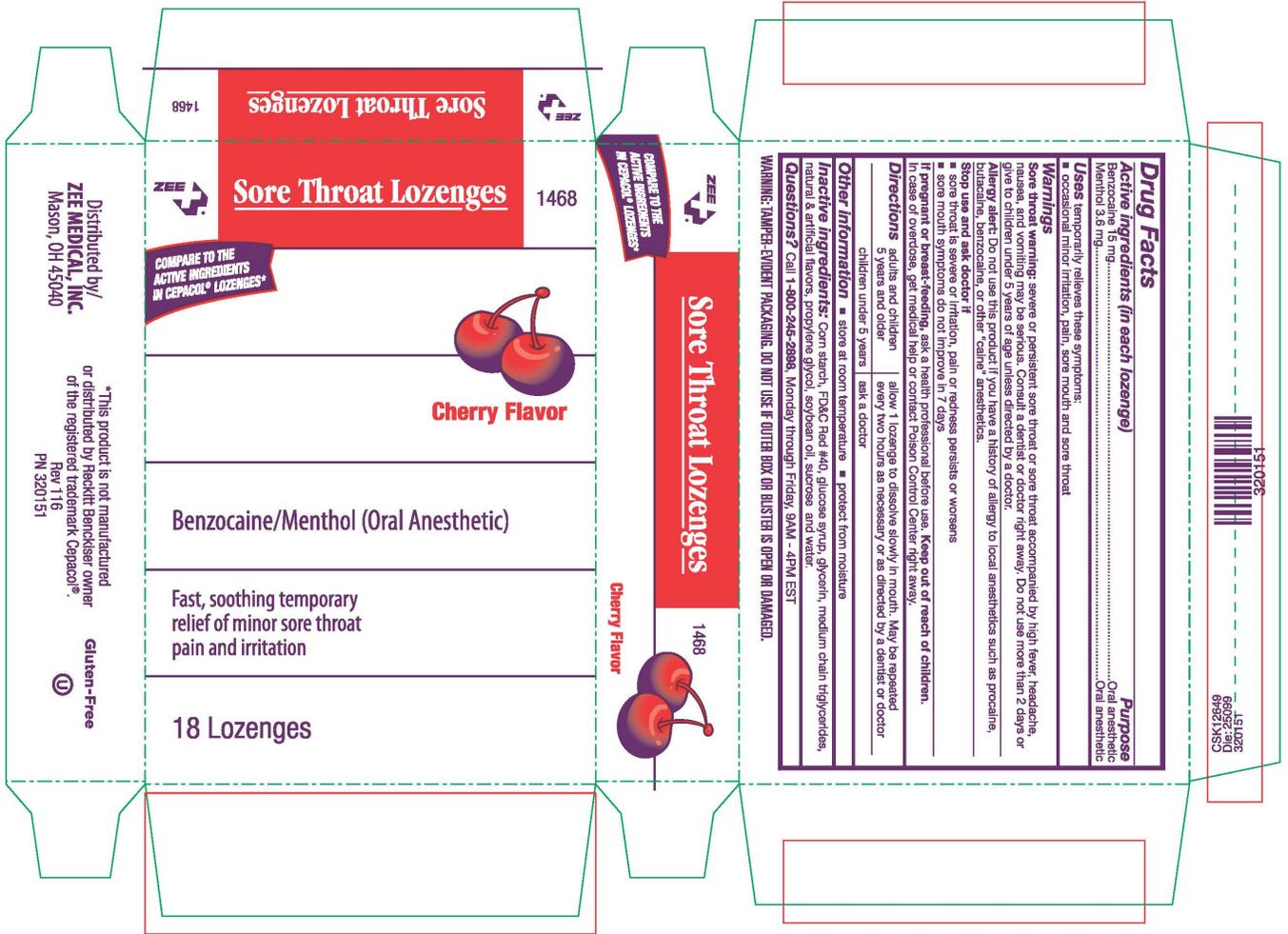
Directions

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

Inactive ingredients: Corn starch, FD&C red no. 40, glucose syrup, glycerin, medium chain triglycerides, natural and artificial flavors, propylene glycol, soybean oil, sucrose and water.

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



JOB INFORMATION
 CUSTOMER: Bestco
 JOB# NA
 PO #
 FILE NAME: 320151_J147257
 DATE: 4/14/2016
 TIME: 1:25 PM
 DIE, TRIM SIZE:
 HEIGHT +6.2828 WIDTH +8.8046
 EPP # 919672
 DIE # 25099
 MPS LEGEND Vinyl #

PROOFING CHECK LIST

- Color Placement
- Copy (Spelling, Fonts)
- Barcode
- Part# / Revision level
- Graphics

PROOF APPROVAL

- I approve & proceed with order please sign and date
 Please make change & reproof
- Please review proofing checklist before signing and dating.

PLEASE NOTE:
 PANTONES or special metallics
 used in this proof may not match
 the PANTONES and color standards.
 Use the current PANTONER swatch
 guide for the most accurate color
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CHERRY THROAT RELIEF LOZENGES

benzocaine lozenge

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:35418-010

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.6 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	17mm
Flavor	CHERRY	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:35418-010-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/14/2016	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/14/2016	

Labeler - Zee Medical (009645623)

Registrant - Bestco Inc. (002149136)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(35418-010)