

CHERRY SORE THROAT LOZENGE- benzocaine lozenge

Geiss, Destin & Dunn

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 ingredients (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, persist 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 two 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? Or to report an adverse event call **1-800-245-2898**. Monday through Friday, 9am to 4pm EST

GOODSENSE®

Fast Acting

Sore Throat Lozenges

Menthol/Benzocaine - Oral Anesthetic

18 Lozenges

CHERRY FLAVOR

GOODSENSE®

Fast Acting

Sore Throat Lozenges

Menthol/Benzocaine - Oral Anesthetic

- Temporarily Relieves Sore Throat
- Soothes Mouth Pain

18 Lozenges



*Compare to active ingredients in Cepacol®



CHERRY FLAVOR



GOODSENSE®

Fast Acting

CHERRY FLAVOR

Sore Throat Lozenges

Menthol/Benzocaine - Oral Anesthetic 18 Lozenges

Made in the USA of U.S. and imported ingredients

Distributed by
GEISS, DESTIN & DUNN Inc.
Peachtree City, GA 30269 USA
www.valuelabels.com

Gluten-Free



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PN-320159

Drug Facts

Active ingredients (in each lozenge)
Benzocaine 15 mg
Menthol 3.6 mg
Oral anesthetic

Purpose
Oral anesthetic

Uses
temporarily relieves these symptoms:
occasional minor irritation, pain, sore mouth and sore throat ■ pain associated with canker sores

Warnings
Sore throat warning: severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a dentist or doctor right away. Do not use more than 2 days or give to children under 5 years of age unless directed by a doctor.
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 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
allow 1 lozenge to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor
children under 5 years
ask a doctor

Other information
■ store at room temperature ■ protect from moisture

Inactive ingredients: corn starch, FD&C Red #40, glucose syrup, glycerin, medium chain triglycerides, natural & artificial flavors, propylene glycol, soybean oil, sucrose, and water.

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

* This product is not manufactured or distributed by Heckitt Benckiser owner of the registered trademark Cepacol®. WARNING: TAMPER-EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BUSTER IS OPEN OR DAMAGED.

CSK12649
Dia: 25089
320159



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CHERRY SORE THROAT LOZENGE

benzocaine lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75981-008
Route of Administration	ORAL		

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:75981-008-18	18 in 1 CARTON; Type 0: Not a Combination Product	03/29/2016	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/29/2016	

Labeler - Geiss, Destin & Dunn (076059836)

Registrant - Bestco Inc. (002149136)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(75981-008)