

CHERRY SORE THROAT LOZENGE- benzocaine lozenge

American Sales

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 persist 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

Inactive ingredients: Corn starch, FD&C red # 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



Drug Facts
Active ingredients (in each lozenge)
 Benzocaine 15 mg
 Menthol 3.6 mg

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

Warnings
 Methemoglobinemia warning: Benzocaine may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen in the 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 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 persist or worsens, see your dentist or doctor promptly.

Allergy alerts 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
 ■ pregnant or breastfeeding, 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

Other information
 ■ store at room temperature
 ■ protect from moisture

Drug Facts (continued)
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 Beckitt Benckiser owner of the registered trademark Cepacol®.
 WARNING: TAMPER-EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BUSTER IS OPEN OR DAMAGED.

CAREONE®
 Compare to the active ingredients in Cepacol®
 Extra Strength Sore Throat Cherry®

Extra Strength
Sore Throat & Cough Lozenges

Fast, soothing, temporary relief of minor sore throat pain and irritation

Cherry

18 LOZENGES
 BENZOCAINE 15.0 mg
 MENTHOL 3.6 mg

Cherry

CAREONE®
 Sore Throat & Cough Lozenges

DISTRIBUTED BY: FOODHOLD U.S.A., LLC
 LANDOVER, MD 20785
 MADE IN USA OF U.S. AND IMPORTED INGREDIENTS

For product questions or concerns, contact us at 1-877-646-9949
 ©2018 Alford Dohalze Licensing Sarl
 Quality guaranteed or your money back.

PN-320233
 3 41520 00028 7

CHERRY SORE THROAT LOZENGE

benzocaine lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-043
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.6 mg
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 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:41520-043-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/22/2016	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/22/2016	

Labeler - American Sales (809183973)

Registrant - Bestco Inc. (002149136)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(41520-043)