CHERRY SORE THROAT LOZENGES- benzocaine lozenge Bestco 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.

Benzocaine 15 mg Menthol 3.6 mg

Active ingredients (in each lozenge)

Benzocaine 15 mg

Menthol 3.6 mg

Purposes

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

Other information

- store at room temperature
- protect from moisture

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 - Friday, 9AM to 4PM EST





health sore throat relief 3.6 mg Menthol • 15 mg Benzocaine • Oral Anesthetic



health sore throat relief

3.6 mg Menthol • 15 mg Benzocaine • Oral Anesthetic

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



cherry

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

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

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Drug Facts (continued)

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Stop use and ask doctor if

■ in children under 2 years of age ■ for teething Do not use

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■ headache ■ rapid heart rate ■ shortness of breath ■ dizziness or lightheadedness ■ fatigue or lack of energy 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:

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Drug Facts





BestCo LLC, Mooresville, NC 28115 ©2021

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Oral anesthetic Oral anesthetic Purpose

CHERRY SORE THROAT LOZENGES

benzocaine lozenge

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52642-036

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
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WATER (UNII: 059QF0KO0R)

Product Characteristics

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

Packaging

NDC:52642- 18 in 1 BLISTER PACK; Type 0: Not a Combination 08/15/2018	# Item Code	Package Description	Marketing Start Date	Marketing End Date
030-16 Floudet	1 NDC:52642- 036-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/15/2018	



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/15/2018	
	part356	08/15/2018	

Labeler - Bestco Inc. (002149136)

Registrant - Bestco Inc. (002149136)

Establishment			
Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(52642-036)

Revised: 10/2023 Bestco Inc.