# MIXED BERRY SORE THROAT LOZENGES- benzocaine lozenge Topco Associates

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Benzocaine 7.5 mg Dextromethorphan hydrobromide 5 mg

#### Active ingredient (in each lozenge)

Benzocaine 7.5 mg

Dextromethorphan hydrobromide 5 mg

#### **Purposes**

Oral Pain Reliever

Cough Suppressant

**Uses** temporarily relieves these symptoms:

- occasional minor mouth irritation, sore mouth and sore throat
- cough due to minor throat and bronichial irritation as may occur with the common cold

#### **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** if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

- for teething
- in children under 2 years of age

### Ask a doctor before use if you have:

- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)

### Stop use and ask doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling develops
- cough lasts for more than 7 days, comes back, or occurs with fever, rash, or persistent headache.

These could be signs of a serious condition.

**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 12 years and older - Allow 2 lozenges to dissolve slowly in mouth, one at a time; may be repeated every 4 hours, not to exceed 12 lozenges in 24 hours, or as directed by a doctor

children 6 to 12 years - take 1 lozenge and allow to dissolve slowly in the mouth; may be repeated every 4 hours, not to exceed 6 lozenges in 24 hours, or as directed by a doctor

children under 6 years of age - do not use

#### Other information

- store at room temperature
- protect from moisture

**Inactive ingredients:** Acesulfame potassium, corn starch, corn syrup, FD&C blue no. 1, FD&C red no. 40, glycerin, medium chain triglycerides, natural and artificial flavors, propylene glycol, soybean oil, sucrose and water.

Questions? Or to report an adverse event call 1-888-423-0139

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Drug Facts



COMPARE TO CEPACOL® **ACTIVE INGREDIENTS** 

**Sore Throat &** Cough Lozenges

BENZOCAINE 7.5mg DEXTROMETHORPHAN HBr 5mg

#### TEMPORARY RELIEF OF:

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Purposes

- Minor Sore Throat and Mouth Irritation
- Cough Due to Minor Throat and Bronchial Irritation



18 LOZENGES

MIXED BERRY **FLAVOR** 

actual size

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

Questions? Or to report an adverse event call 1-888-423-0139

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Drug Facts (continued)

children under 6 years of age not to exceed 6 lozenges in 24 hours, or as directed by a doctor take it lozenge and allow to dissolve slowly in the mouth; may be repeated every 4 hours, children 6 to 12 years of age not to exceed 12 lozenges in 24 hours, or as directed by a doctor 12 years and older

Allow 2 lozenges to dissolve slowly in mouth, one at a lime; may be repeated every 4 hours, DIRECTIONS adults and children 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.

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Methemoglobinemia warning: Warnings

Drug Facts (continued)





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# **MIXED BERRY SORE THROAT LOZENGES**

benzocaine lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-836
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	7.5 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg	

Inactive Ingredients		
Ingredient Nar	ne Strength	
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	red (Purplish Red)	Score	no score
Shape	ROUND	Size	17mm
Flavor	BERRY	Imprint Code	В
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800- 836-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	08/03/2018	



Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	08/03/2018	

# Labeler - Topco Associates (006935977)

# Registrant - Bestco Inc. (002149136)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bestco Inc.		002149136	manufacture(36800-836)	

Revised: 11/2024 Topco Associates