

## **RITE AID MIXED BERRY SORE THROAT AND COUGH LOZENGE-**

### **benzocaine lozenge**

**Rite Aid**

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**Benzocaine 7.5 mg**

**Dextromethorphan Hydrobromide 5 mg**

#### **Active ingredients (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 bronchial 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 a doctor if

- sore mouth symptoms do not improve in 7 days
- irritation, pain, or redness persists or worsens
- swelling develops
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

**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 of age - 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 **1-800-245-2898**, Monday - Friday, 9AM to 4PM EST



No Ink or ( Lot/Exp

**Benzocaine 7.5 mg Dextromethorphan HBr 5 mg**

TEMPORARY RELIEF OF:  
 Minor sore throat & mouth irritation  
 Cough due to minor throat & bronchial irritation



MIXED BERRY



**18**  
 LOZENGES



PN-320257



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

**Drug Facts (continued)**  
**Other information** ■ store at room temperature ■ protect from moisture  
**Inactive ingredients** Acesulfame potassium, corn starch, com syrup, FD&C Blue 1, FD&C Red 40, glycerin, medium chain triglycerides, natural and artificial flavor, polyethylene glycol, soybean oil, sucrose and water.  
**Questions?** Or to report an adverse event call 1-800-421-2238, Monday through Friday, 9AM - 4PM EST

**Drug Facts (continued)**  
**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.  
**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 a doctor if**  
 ■ some mouth symptoms do not improve in 7 days ■ irritation, pain, or redness persists or worsens  
 ■ swelling develops ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.  
**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**  
 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 8 to 12 years of age  
 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

No Ink or Coating

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**RITE AID MIXED BERRY SORE THROAT AND COUGH LOZENGE**

benzocaine lozenge

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-0043
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (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 Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	purple (Purplish red)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	17mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	B
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0043-1	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/18/2019	



### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/18/2019	

**Labeler** - Rite Aid (014578892)

**Registrant** - Bestco Inc. (002149136)

### Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc.		002149136	manufacture(11822-0043)