

MIXED BERRY SORE THROAT LOZENGES- benzocaine lozenge

Topco Associates

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 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 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 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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Dextromethorphan hydrobromide 5mg
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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



COMPARE TO CEPACOL[®]
ACTIVE INGREDIENTS*

Sore Throat & Cough Lozenges

BENZOCAINE 7.5mg
DEXTROMETHORPHAN HBr 5mg

TEMPORARY RELIEF OF:

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



actual size

18 LOZENGES

MIXED BERRY FLAVOR

WARNING: TAMPER-EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BLISTER IS OPEN OR DAMAGED.

Drug Facts (continued)
Other information ■ store at room temperature ■ protect from moisture
Inactive ingredients Acacia, gum, polyethylene glycol, corn syrup, FD&C Blue 1, FD&C Red 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
This product is not manufactured or distributed by Reckitt Benckiser owner of the registered trademark Cepacol.

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) ■ fatigue or lack of energy ■ swelling, nausea, or vomiting, consult a doctor promptly. If sore throat 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.
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■ 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 throat symptoms do not improve in 7 days ■ irritation, pain, or redness persists or worsens
■ swelling develops ■ cough lasts more than 7 days, 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
Allow 2 lozenges to dissolve slowly in mouth, one at a time; may be repeated every 4 hours.
12 years and older
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

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AND IMPORTED INGREDIENTS.
QUALITY GUARANTEED
GF GLUTEN FREE

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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	red (Purplish Red)	Score	no score
Shape	ROUND	Size	17mm
Flavor	BERRY	Imprint Code	B
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 not final	part356	08/03/2018	

Labeler - Topco Associates (006935977)

Registrant - Bestco Inc. (002149136)

Establishment

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