

MIXED BERRY SORE THROAT AND COUGH LOZENGE- benzocaine lozenge **Dollar General Corporation**

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 ingredients (in each lozenge)

Benzocaine 7.5 mg

Dextromethorphan hydrobromide 5 mg

Purpose

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 a 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, nausea or vomiting contact 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 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 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

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 Coating

100% Satisfaction Guaranteed! and imported ingredients. **Gluten-Free**  Made in USA or U.S. (888) 309-9030
 DISTRIBUTED BY DOLGOCORP, LLC
 100 MISSION RIDGE
 GOODLETTSVILLE, TN 37072
 PN-320217 A0891 0 70312 36054 3

Drug Facts (continued)

Warnings
Metformin hydrochloride warning: Metformin hydrochloride may cause 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 7 days, is accompanied or followed by fever, headache, rash, 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, butaine, 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 you prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have:
 ■ a cough that occurs with smoking, asthma, or emphysema
 ■ a 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. In case of overdose, get medical help or contact Poison Control Center right away.

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

Drug Facts (continued)

Other information ■ store at room temperature ■ protect from moisture

Inactive ingredients Acosulfame potassium, corn starch, FD&C Red 40, glycerin, medium chain triglycerides natural and artificial flavors, polyethylene glycol, soybean oil, sucrose and water.

Questions? Or to report an adverse event, call 1-800-245-2988, 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 BLISTER IS OPEN OR DAMAGED.**

Compare to the active ingredient of Cepacol®



Sore Throat Lozenges

Benzocaine, 7.5 mg
 Oral Pain Reliever
 Dextromethorphan NBr, 5 mg
 Cough Suppressant

- Relieves:
- Minor sore throat and mouth irritation
 - Cough due to minor throat and bronchial irritation



Mixed Berry Flavor

18 Lozenges

Actual Lozenge Size



Drug Facts

Active ingredients (in each lozenge)
 Benzocaine 7.5 mg
 Dextromethorphan hydrobromide 5 mg

Uses temporarily relieves these symptoms:
 ■ occasional minor mouth irritation, sore mouth and sore throat
 ■ cough due to minor throat and bronchial irritation as they occur with the common cold

Purposes
 Oral Pain Reliever
 Cough Suppressant

No Lot/Exp Info

No Ink or Coating

MIXED BERRY SORE THROAT AND COUGH LOZENGE

benzocaine lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-066
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: 9D2RT19KYH) (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:55910-066-18	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	05/13/2016	



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	05/13/2016	

Labeler - Dollar General Corporation (068331990)

Registrant - Bestco Inc. (002149136)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco Inc		002149136	manufacture(55910-066)

Revised: 11/2021

Dollar General Corporation