

CVS SORE THROAT MIXED BERRY FLAVOR- benzocaine, dextromethorphan hydrobromide lozenge
CVS Pharmacy, 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.

CVS Mixed Berry Sore Throat

CVS Sore Throat Mixed Berry Flavor

<i>Active ingredients (in each lozenge)</i>	<i>Purpose</i>
Benzocaine 7.5 mg	Oral Pain Reliever
Dextromethorphan hydrobromide 5 mg	Oral Pain Reliever

Uses

temporarily relieves these symptoms:

- occasional minor irritation, pain, sore mouth and sore throat
- pain associated with canker sores
- cough due to minor throat and bronchial irritation as may occur with common cold

Warnings

Allergy Alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or any other "caine" anesthetics.

Sore throat warning:

Severe or persistent sore throat or sore throat accompanied by high fever, headache, rash, nausea, and vomiting may be serious. Consult a dentist or doctor right away. Do not use more than 2 days or administer to children under 5 years of age unless directed by a doctor.

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, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

Stop Use and ask a doctor or dentist if

- sore mouth symptom 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 is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep this and all drugs out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- adults and children 12 years and older: take 2 lozenges (one immediately after the other) 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 6 to under 12 years of age: take 1 lozenge and allow to dissolve slowly in the mouth; may be repeated every 4 hours
- children 6 years of age: do not use

Other information

- store at room temperature
- protect from moisture

Inactive ingredients

Acesulfame potassium, corn syrup, FD&C Blue #1, FD&C Red #40, natural and artificial flavors (medium chain triglycerides), propylene glycol, sucrose, and water. Soybean oil and corn starch used as processing aids.

Questions ?

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

CVS Sore Throat Lozenges Mixed Berry Flavor 18 Count (59779-649-18)

CVS pharmacy

compare to the active ingredients in Cepacol**

SORE THROAT &

COUGH LOZENGES

SOOTHING RELIEF

BENZOCAINE 7.5 mg/DEXTROMETHORPHAN HBr 5 mg

Temporarily relieves:

- Minor sore throat & mouth irritation
- Cough due to minor throat irritation

Mixed Berry Flavor

18 LOZENGES

DISTRIBUTED BY:

CVS Pharmacy, Inc.

One Cvs Drive Woonsocket, RI 02895

2014 CVS/Pharmacy

CVS.com 1-800-SHOP CVS

Made in the USA

This product is not manufactured or distributed
by Reckitt Benckiser owner of the registered
trademark Cepacol.



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

Drug Facts

Active ingredients (in each lozenge)

Benzocaine 7.5 mg.....	Oral Pain Reliever
Dextromethorphan hydrobromide 5mg.....	Cough Suppressant

Uses

- temporarily relieves these symptoms:
- occasional minor mouth irritation, sore mouth and sore throat ■ pain associated with canker sores
 - cough due to minor throat and bronchial irritation as may occur with the common cold

Warnings

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.

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 consult a doctor promptly.

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 ■ in a child under 6 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 or dentist 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 this and all drugs 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	take 2 lozenges (one immediately after the other) 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 6 to 12 years of age	take 1 lozenge and allow to dissolve slowly in the mouth; may be repeated every 4 hours
children 6 years of age	do not use

Drug Facts (continued)

Other information ■ store at room temperature ■ protect from moisture

Inactive ingredients: Acesulfame potassium, corn syrup, FD&C Blue 1, FD&C Red 40, natural and artificial flavors (medium chain triglycerides), propylene glycol, sucrose, and water. Soybean oil and corn starch used as processing aids.

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

CVS SORE THROAT MIXED BERRY FLAVOR

benzocaine, dextromethorphan hydrobromide lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-649
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOC AINE (UNII: U3RSY48JW5) (BENZOC AINE - UNII:U3RSY48JW5)	BENZOC AINE	7.5 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CORN SYRUP (UNII: 9G5L16BK6N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	
SOYBEAN OIL (UNII: 241ATL177A)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	purple	Score	no score
Shape	ROUND	Size	23mm
Flavor	BERRY	Imprint Code	B
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-649-18	18 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	04/22/2014	

Labeler - CVS Pharmacy, Inc. (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
Bestco, Inc.		002149136	manufacture(59779-649)

Revised: 4/2014

CVS Pharmacy, Inc.