

**CEPACOL EXTRA STRENGTH SORE THROAT AND COUGH- benzocaine and dextromethorphan hydrobromide lozenge**  
**RB Health (US) LLC**

*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.*

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**Cēpacol<sup>®</sup>**  
**Extra Strength Sore Throat & Cough**

***Drug Facts***

<b><i>Active ingredients (in each lozenge)</i></b>	<b><i>Purposes</i></b>
Benzocaine 7.5 mg	Oral pain reliever
Dextromethorphan HBr 5 mg	Cough suppressant

**Uses**

For the temporary relief of occasional

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

**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

**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, swelling, 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.
- for teething
- in children 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 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 a Poison Control Center right away.

**Do not exceed recommended dosage.**

## Directions

adults and children 12 years of age and older	take 2 lozenges (one immediately after the other) and allow each lozenge to dissolve slowly in the mouth; may be repeated every 4 hours as needed, not to exceed 12 lozenges in 24 hours, or as directed by a doctor or dentist
children 6 to under 12 years of age	take 1 lozenge and allow product to dissolve slowly in the mouth; may be repeated every 4 hours as needed, not to exceed 6 lozenges in 24 hours, or as directed by a doctor or dentist
children under 6 years of age	do not use

## Other information

- store at 20-25°C (68-77°F)
- protect contents from humidity

### **Inactive ingredients**

FD&C blue no. 1, FD&C red no. 40, flavors, isomalt, purified water, sucralose

### **Questions?**

**1-866-682-4639**

You may also report side effects to this phone number.

Dist. by: RB Health (US)  
Parsippany, NJ 07054-0224

### **PRINCIPAL DISPLAY PANEL - 16 Lozenge Blister Pack Carton**

NDC 63824-744-16  
READ ALL WARNINGS

Cēpacol®  
EXTRA STRENGTH

#1  
DOCTOR  
RECOMMENDED †

SORE THROAT & COUGH

Benzocaine 7.5 mg Oral Pain Reliever | Dextromethorphan HBr 5 mg Cough Suppressant

- Relieves Sore Throat Pain
- Quiets Cough • Fast Acting
- Maximum Numbing\*

16 Lozenges mixed berry

\*based on amount of benzocaine per adult dose

# Ink & Varnish Free Area

3036810

**SORE THROAT & COUGH**



**PARENTS:**  
Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

**Cēpacol. EXTRA STRENGTH**

Tamper evident. Do not use if carton is damaged or if primed seal on blister is broken or missing.

<p><b>Drug Facts</b> (continued)</p> <p><b>Other Information</b> ■ Store at 20-25°C (68-77°F) ■ product contents to remain humidity controlled, unopened, until the use-by date.</p>	
<p><b>Directions</b></p> <p>Do not exceed recommended dosage.</p> <p>In case of overdose, get medical help or contact a Poison Control center either right away or at night.</p> <p>If pregnant or breastfeeding, ask a health professional for advice.</p> <p>Keep out of reach of children.</p> <p>Use as directed. These could be signs of a serious condition:</p> <ul style="list-style-type: none"> <li>■ cough lasts more than 7 days, comes back, or occurs with fever, rash,</li> <li>■ irritation, pain, or redness persists or worsens ■ swelling develops</li> <li>■ sore mouth symptoms do not improve in 7 days</li> </ul> <p>Stop use and ask a doctor or dentist if:</p> <ul style="list-style-type: none"> <li>■ cough that occurs with a runny nose (rhinorrhea),</li> <li>■ asthma, or emphysema</li> <li>■ persistent or chronic cough such as occurs with smoking.</li> </ul> <p>Ask a doctor before use if you have:</p> <ul style="list-style-type: none"> <li>■ a history of asthma</li> <li>■ a history of seizures</li> <li>■ a history of heart disease</li> <li>■ a history of kidney disease</li> <li>■ a history of liver disease</li> <li>■ a history of stomach or intestinal disease</li> <li>■ a history of diabetes</li> <li>■ a history of low blood sugar</li> <li>■ a history of high blood pressure</li> <li>■ a history of glaucoma</li> <li>■ a history of narrow-angle glaucoma</li> <li>■ a history of epilepsy</li> <li>■ a history of alcoholism</li> <li>■ a history of drug abuse</li> <li>■ a history of taking medicine to control seizures</li> <li>■ a history of taking medicine to control blood pressure</li> <li>■ a history of taking medicine to control heart rate</li> <li>■ a history of taking medicine to control cholesterol</li> <li>■ a history of taking medicine to control blood sugar</li> <li>■ a history of taking medicine to control diabetes</li> <li>■ a history of taking medicine to control high blood pressure</li> <li>■ a history of taking medicine to control glaucoma</li> <li>■ a history of taking medicine to control epilepsy</li> <li>■ a history of taking medicine to control alcoholism</li> <li>■ a history of taking medicine to control drug abuse</li> </ul>	<p><b>Warnings</b></p> <p>Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in the blood. This can occur even if you have used the product before.</p> <p>Stop use and seek immediate medical attention if you or a child in your household experiences:</p> <ul style="list-style-type: none"> <li>■ pale, gray, or blue-colored skin (cyanosis)</li> <li>■ headache</li> <li>■ rapid heart rate</li> <li>■ shortness of breath</li> <li>■ dizziness or lightheadedness</li> <li>■ fatigue or lack of energy</li> </ul> <p>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.</p> <p>See throat warning: If sore throat lasts more than 2 weeks, as accompanied or followed by fever, headache, rash, swelling, or difficulty swallowing, see your doctor.</p> <p>Do not use if you are now taking a prescription medication or if you are taking MAOI (certain drugs for depression, Parkinson's disease, or for 2 weeks after stopping the MAOI) (certain drugs for depression, Parkinson's disease, or for 2 weeks after stopping the MAOI) (certain drugs for depression, Parkinson's disease, or for 2 weeks after stopping the MAOI) (certain drugs for depression, Parkinson's disease, or for 2 weeks after stopping the MAOI).</p> <p>If you do not know what your prescription drug contains, ask your pharmacist for help.</p>

**#1 DOCTOR RECOMMENDED\***

# Cēpacol. EXTRA STRENGTH

**SORE THROAT & COUGH**

mixed berry

NDC 63824-744-16

**READ ALL WARNINGS**

# Cēpacol. EXTRA STRENGTH

**SORE THROAT & COUGH**

Benzocaine 7.5 mg Oral Pain Reliever | Dextromethorphan HBr 5 mg Cough Suppressant

- Relieves Sore Throat Pain
- Quiets Cough • Fast Acting
- Maximum Numbing\*

## 16 Lozenges mixed berry

\*based on amount of benzocaine per adult dose

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**HEALTH • HYGENE • HOME**

Dist. by: RB Health (US)  
Parsippany, NJ 07054-0224  
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Made in India

**Questions?**  
1-866-682-4639  
You may also report side effects to this phone number.

**www.cepacol.com**

\*Cēpacol is the #1 Doctor Recommended OTC Sore Throat Lozenge in the U.S. for the period of June 1, 2017 to May 31, 2018 (IQVIA ProVoice Survey)

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**CEPACOL EXTRA STRENGTH SORE THROAT AND COUGH**  
benzocaine and dextromethorphan hydrobromide lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-744
<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>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>ISOMALT</b> (UNII: S870P55O2W)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	18mm
<b>Flavor</b>	BERRY	<b>Imprint Code</b>	S
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-744-16	2 in 1 CARTON	05/05/2014	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-744-94	1 in 1 CARTON	05/05/2014	04/14/2024
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63824-744-36	3 in 1 CARTON	05/01/2019	04/14/2024
3		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part356	05/05/2014	

**Labeler** - RB Health (US) LLC (081049410)

Revised: 9/2023

RB Health (US) LLC