

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

Cēpacol®
Extra Strength Sore Throat & Cough

Drug Facts

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

Uses

Uses

temporarily relieves

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

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

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

PRINCIPAL DISPLAY PANEL - 16 Lozenge Blister Pack Carton

NDC 63824-744-16

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 flavor

*based on amount of benzocaine per adult dose



Cēpacol[®]

EXTRASTRENGTH

**SORE THROAT
& COUGH**

mixed berry
flavor



NDC 63824-744-16

Cēpacol[®]

EXTRASTRENGTH



Not actual size



SORE THROAT & COUGH

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

- Relieves Sore Throat Pain
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16 Lozenges

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berry flavor



*based on amount of benzocaine per adult dose

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Made in England
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www.cepacol.com

† Cepacol is the #1 Doctor Recommended OTC Sore Throat Lozenge in the U.S. for the period of March 1, 2023 to Feb 29, 2024.
(IQVIA ProVoice survey)



Patents: www.reckitt.com/patents

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SORE THROAT & COUGH

mixed berry flavor

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Cepacol
EXTRA STRENGTH
tamper evident. Do not use if carton is damaged or if printed seal on blister is broken or missing.

Drug Facts

Active ingredients (in each lozenge) Purposes
Benzocaine 7.5 mg..... Oral pain reliever
Dextromethorphan HBr 5 mg..... Cough suppressant

Uses temporarily relieves
 ■ cough due to minor throat and bronchial irritation as may occur with the common cold
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 ■ for teething ■ in children under 6 years of age

Drug Facts (continued)

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Ask a doctor before use if you have
 ■ persistent or chronic cough such as occurs with smoking, asthma, or emphysema
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Stop use and ask a doctor or dentist if
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Directions ■ dose as follows or as directed by a doctor or dentist

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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, maltitol, propylene glycol, purified water, sodium bicarbonate, sucralose

CEPACOL EXTRA STRENGTH SORE THROAT AND COUGH

benzocaine and dextromethorphan hydrobromide lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-744
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ISOMALT (UNII: S870P55O2W)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

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

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

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	05/05/2014	

Labeler - RB Health (US) LLC (081049410)

Revised: 3/2025

RB Health (US) LLC