

CEPACOL EXTRA STRENGTH SORE THROAT CHERRY- benzocaine and menthol 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.

Cēpacol®
Extra Strength Sore Throat cherry

Drug Facts

Active ingredients (in each lozenge)	Purposes
Benzocaine 15 mg	Oral pain reliever
Menthol 3.6 mg	Oral pain reliever

Uses

For the temporary relief of occasional

- 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

- for teething
- in children under 5 years of age

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, rash, or fever develops

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 5 years of age and older: allow one lozenge to dissolve slowly in the mouth; may be repeated every 2 hours as needed or as directed by a doctor or dentist.
- children under 5 years of age: do not use

Other information

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

Inactive ingredients

D&C red no. 33, FD&C red no. 40, flavors, isomalt, maltitol, propylene glycol, purified water, sodium bicarbonate, 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

Made in England

PRINCIPAL DISPLAY PANEL - 16 Lozenge Blister Pack Carton

NDC 63824-713-16
READ ALL WARNINGS

Cēpacol®
EXTRA STRENGTH

#1
DOCTOR
RECOMMENDED†

SORE THROAT

Benzocaine 15 mg • Menthol 3.6 mg | Oral Pain Relievers

- Relieves Sore Throat Pain
- Fast Acting
- Maximum Numbing*

16 Lozenges cherry

*based on amount of benzocaine per dose

Ink & Varnish Free Area

Drug Facts
Active ingredients (in each lozenge) Purposes
 Benzocaine 15 mg Oral pain reliever
 Menthol 3.6 mg Oral pain reliever

Uses
 For the temporary relief of occasional sore throat, sore mouth, minor irritation, and pain associated with canker sores.

Warnings
 Methemoglobinemia warning: Use of the 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 throats warning: If a 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.

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

Inactive ingredients D&C red no. 33, FD&C red no. 40, flavors, isomalt, maltitol, propylene glycol, purified water, sodium bicarbonate, sucralose

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Directions
 ■ adults and children 5 years of age and older: allow one lozenge to dissolve slowly in the mouth; may be repeated every 2 hours as needed or as directed by a doctor or dentist.
 ■ children under 5 years of age: do not use

Do not use
 ■ in children under 5 years of age
 ■ for teething

Do not exceed recommended dosage.
 In case of overdose, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.
 If pregnant or breast-feeding, ask a health professional before use.
 ■ swelling, rash, or fever develops
 ■ sore throat, ■ sore mouth, ■ minor irritation, ■ pain
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 ■ sore throat, ■ sore mouth, ■ minor irritation, ■ pain

Stop use and ask a doctor or dentist if
 ■ sore mouth symptoms do not improve in 7 days
 ■ sore throat symptoms do not improve in 7 days

Cepacol
EXTRA STRENGTH
SORE THROAT
 cherry

#1 DOCTOR RECOMMENDED
Cepacol
EXTRA STRENGTH
 cherry

NDC 63824-713-16

READ ALL WARNINGS

Cepacol
EXTRA STRENGTH

SORE THROAT
 Benzocaine 15 mg • Menthol 3.6 mg | Oral Pain Relievers

- Relieves Sore Throat Pain
- Fast Acting
- Maximum Numbing*

16 Lozenges cherry
 *based on amount of benzocaine per dose

Lot No.:
 Lane 1
 Lane 2
 Lane 3

Exp. Date:
 Lane 1
 Lane 2
 Lane 3

www.cepacol.com
 †Cepacol 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)

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

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Patents: www.rb.com/patents

CEPACOL EXTRA STRENGTH SORE THROAT CHERRY
 benzocaine and menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-713
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	15 mg
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	3.6 mg

Inactive Ingredients

Ingredient Name	Strength
D&C red no. 33 (UNII: 9DBA0SBB0L)	
FD&C red no. 40 (UNII: WZB9127XOA)	
isomalt (UNII: S870P55O2W)	
maltitol (UNII: D65DG142WK)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0K00R)	
sodium bicarbonate (UNII: 8MDF5V39QO)	
sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	18mm
Flavor	CHERRY	Imprint Code	S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-713-16	2 in 1 CARTON	07/15/2013	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-713-94	1 in 1 CARTON	07/15/2013	
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63824-713-04	1 in 1 CARTON	07/15/2013	
3		4 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 NOT FINAL	part356	07/15/2013	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022

RB Health (US) LLC