

**CEPACOL EXTRA STRENGTH SORE THROAT SUGAR FREE 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.*

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**Cēpacol<sup>®</sup>**  
**Extra Strength Sore Throat sugar free cherry**

**Drug Facts**

<b>Active ingredients (in each lozenge)</b>	<b>Purposes</b>
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**

Sugar Free

For Institutional Use – Not For Resale

READ ALL WARNINGS

NDC 63824-722-82

Cēpacol<sup>®</sup>  
EXTRA STRENGTH  
SORE THROAT

Benzocaine 15 mg | Menthol 3.6 mg

Oral Pain Relievers

cherry

16 Lozenges

Ink & Varnish Free Area

**Drug Facts**

**Active Ingredients (in each lozenge)** **Purposes**  
 Benzocaine 15 mg, 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**  
 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 for 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 at warning:** If sore throat is severe, persists for more than 2 days, is accompanied by fever, headache, rash, swelling, nausea, or vomiting, consult a doctor promptly.

**Drug Facts (cont. Inued)**  
 Do not use  
 ■ in children under 5 years of age  
 ■ if teaching  
 ■ 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  
 ■ mouth is painful, or redness persists or worsens  
 ■ irritation, rash, or fever develops

**Keep out of reach of children.**  
 In case of overdose, get medical help or contact 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, polyethylene glycol, purified water, sodium bicarbonate, sucralose

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

**Sugar Free**

**Cēpacol.**  
**EXTRASTRENGTH**

**SORE THROAT**  
 Cherry

For Institutional Use - Not For Resale

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

**Sugar Free**

**Cēpacol.**  
**EXTRASTRENGTH**

**SORE THROAT**  
 cherry

For Institutional Use - Not For Resale

**Sugar Free**

For Institutional Use - Not For Resale

**READ ALL WARNINGS**

NDC 63824-722-82

**Cēpacol.**  
**EXTRASTRENGTH**  
**SORE THROAT**

Benzocaine 15 mg | Menthol 3.6 mg  
 Oral Pain Relievers

**cherry**

**16 Lozenges**

Lot No.:

Lane 1  
 Lane 2  
 Lane 3

Exp. Date:

Lane 1  
 Lane 2  
 Lane 3

**Sugar Free**

**Cēpacol.**  
**EXTRASTRENGTH**



[www.cepacol.com](http://www.cepacol.com)  
 Dist. by: RB Health (US)  
 Parsippany, NJ  
 07054-0224  
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 Patents: [www.rb.com/patents](http://www.rb.com/patents)  
 021319 3085813

**CEPACOL EXTRA STRENGTH SORE THROAT SUGAR FREE CHERRY**  
 benzocaine and menthol lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63824-722
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	3.6 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<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>	CHERRY	<b>Imprint Code</b>	S
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63824-722-16	2 in 1 CARTON	07/15/2013	06/30/2019
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-722-83	24 in 1 CARTON	07/15/2013	07/01/2021
2	NDC:63824-722-82	2 in 1 CARTON		
2		8 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>
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OTC monograph not final	part356	07/15/2013	09/01/2024
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**Labeler** - RB Health (US) LLC (081049410)

Revised: 9/2023

RB Health (US) LLC