

**CEPACOL EXTRA STRENGTH SORE THROAT TANGERINE- benzocaine and menthol,  
unspecified form 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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**Cepacol®  
Extra Strength Sore Throat Tangerine**

***Drug Facts***

<b><i>Active ingredients (in each lozenge)</i></b>	<b><i>Purposes</i></b>
Benzocaine 15 mg	Oral pain reliever
Menthol 2.3 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**

FD&C yellow no. 6, 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 63824-768-16

READ ALL WARNINGS

Cēpacol®  
EXTRA STRENGTH

#1  
DOCTOR  
RECOMMENDED†

SORE THROAT

Benzocaine 15 mg • Menthol 2.3 mg | Oral Pain Relievers

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

16 Lozenges tangerine

\*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 2.3 mg ..... Oral pain reliever

**Uses**  
For the temporary relief of occasional sore throat, sore mouth, minor irritation, 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 if you or a child in your care develops:  
pale, gray, or blue colored skin (cyanosis), 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.

**Drug Facts (continued)**  
Do not use  
■ in children under 5 years of age  
■ for teething

**Purposes**  
■ in children under 5 years of age  
■ for teething

**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

**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**  
FD&C yellow no. 6, flavors, sorbitol, maltitol, propylene glycol, purified water, sodium bicarbonate, sucralose

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

**Cepacol**  
EXTRASTRENGTH  
SORE THROAT  
tangerine

**16 Lozenges tangerine**  
\*based on amount of benzocaine per dose

**www.cepacol.com**

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

Patents: www.rb.com/patents

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**#1 DOCTOR RECOMMENDED\***

# Cepacol

EXTRASTRENGTH

SORE THROAT

Benzocaine 15 mg • Menthol 2.3 mg | Oral Pain Relievers

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READ ALL WARNINGS

NDC 63824-768-16

Lot No.: Lane 1 Lane 2 Lane 3

Exp. Date: Lane 1 Lane 2 Lane 3

3 63824 76816 8

# CEPACOL EXTRA STRENGTH SORE THROAT TANGERINE

benzocaine and menthol, unspecified form lozenge

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-768
Route of Administration	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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	2.3 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C yellow no. 6</b> (UNII: H77VEI93A8)	
<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

Color	ORANGE	Score	no score
Shape	ROUND	Size	18mm
Flavor	TANGERINE	Imprint Code	S
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-768-16	2 in 1 CARTON	07/15/2015	
1		8 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	07/15/2015	

Labeler - RB Health (US) LLC (081049410)

