

CEPACOL SORE THROAT- benzocaine and menthol lozenge
Reckitt Benckiser 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®
Sore Throat

Drug Facts

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

Uses

temporary relief of occasional

- sore throat
- sore mouth
- minor mouth irritation
- pain associated with canker sores

Warnings

Allergy alert

- Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or any 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, nausea or vomiting consult a doctor promptly.

Do not use in a child 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 this and all drugs out of the 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 or older: allow 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

- tamper evident: product is sealed in blister package for your protection. Do not use if carton is damaged or if printed seal on blister is broken or missing.
- store at room temperature 20-25°C (68-77°F)
- protect contents from humidity

Inactive ingredients

D&C Red #33, FD&C Red #40, flavors, isomalt, maltitol, propylene glycol, purified water, sodium bicarbonate, sucralose

Questions?

Call 1-888-963-3382

You may also report side effects to this phone number.

Dist. by:
Reckitt Benckiser
Parsippany, NJ
07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 16 Lozenges Carton

NDC 63824-712-16

NEW FORMULA!

Cēpacol[®]

SORE THROAT

Benzocaine 15 mg | Menthol 3.6 mg

Oral Pain Reliever

- **Instant Acting**
- **Maximum Strength Numbing**

16 Lozenges

cherry

Ink & Varnish Free Area

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SORE THROAT
Cepacol
8086914
cherry

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SORE THROAT

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NDC 63824-712-16

Cepacol

SORE THROAT

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Oral Pain Reliever

- Instant Acting
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16 Lozenges

cherry



Lot No.:
Lane 1
Lane 2
Lane 3
Exp. Date:
Lane 1
Lane 2
Lane 3

Cepacol
SORE THROAT

cherry

CEPACOL SORE THROAT
benzocaine and menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-712
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzocaine (UNII: U3RSY48JW5) (Benzocaine - UNII:U3RSY48JW5)	Benzocaine	15 mg
Menthol (UNII: L7T10EIP3A) (Menthol - UNII:L7T10EIP3A)	Menthol	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:63824-712-16	2 in 1 CARTON		
1		8 in 1 BLISTER PACK		
2	NDC:63824-712-98	72 in 1 CARTON		
2		8 in 1 BLISTER PACK		
3	NDC:63824-712-94	1 in 1 CARTON		
3		4 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part356	03/15/2013	

