

SORE THROAT LOGENZES SORE THROAT- benzocaine and menthol lozenge

Major Pharmaceuticals

Cēpacol[®]

SORE THROAT

Drug Facts

| <i>Active ingredients (in each lozenge)</i> | <i>Purpose</i> |
|--|-----------------------|
| 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: ask a doctor

Other information

- tamper evident packaging: Do not use if outer box or blister is open or damaged.
- store at room temperature
- protect contents from moisture

Inactive ingredients

Glucose syrup, N&A flavoring, propylene glycol, red #40, sucrose, and water. Soybean oil used as processing aid.

Questions?

Call 1-800-616-2471

Dist. by:
Major Pharmaceuticals
Livonia, MI 48150 USA

PRINCIPAL DISPLAY PANEL- 16 Lozenge Carton

NDC 0904-6255-49

MAJOR SORE THROAT LOZENGES**Fast, Long Lasting Relief**

Benzocaine 15 mg | Menthol 3.6 mg
Oral Pain Reliever

18 Lozenges

cherry

MAJOR[®]
Fast, Long Lasting Relief
Sore Throat Lozenges

CHERRY

NDC 0904-6255-49

MAJOR[®]
Fast, Long Lasting Relief
Sore Throat Lozenges

Menthol/Benzocaine

For Temporary Relief of Minor Sore Throat Pain

Oral Anesthetic

18 Lozenges

CHERRY

Compare to the active ingredients in Cepacol[®]

PN-320232



Distributed by
MAJOR[®] PHARMACEUTICALS
17177 N LAUREL PARK DRIVE, SUITE 233,
LIVONIA, MI 48152 USA
M-130 Re-order No. 700608 Rev. 8/18
Gluten-Free

**No Ink or Coating
Lot/Exp Info**

Drug Facts (continued)
Inactive Ingredients Corn starch, FD&C Red #40, glucose syrup, glycerin, medium chain triglycerides, natural & artificial flavors, polyethylene glycol, soybean oil, sucrose and water.
Questions? Call 1-616-247-2474, Monday through Friday 9AM - 4PM EST.
This product is not manufactured or distributed by Redditt Benckis or owner of the registered trademark Cepacol[®].
WARNING: TAMPER-EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BLISTER IS OPEN OR DAMAGED.

Drug Facts

Active ingredients (in each lozenge)

| | |
|-----------------------|-----------------|
| Benzocaine 15 mg..... | Oral anesthetic |
| Menthol 3.6 mg..... | Oral anesthetic |

Purpose

Uses temporarily relieves these symptoms:

- occasional minor irritation, pain, sore mouth and 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

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. If sore mouth symptoms do not improve in 7 days, or if irritation, pain, or redness persist or worsens, see your dentist or doctor promptly.

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.

Do not use

- for teething ■ in children under 2 years of age

Stop use and ask doctor if

- sore throat is severe or irritation, pain or redness persists or worsens ■ sore mouth symptoms do not improve in 7 days

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 Poison Control Center right away.

Directions

adults and children
5 years and older

allow 1 lozenge to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor

children under 5 years

do not use

Other information ■ store at room temperature ■ protect from moisture

SORE THROAT LOZENGES SORE THROAT

benzocaine and menthol lozenge

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0904-6255 |
| 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 |
|--|----------|
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| CORN SYRUP (UNII: 9G5L16BK6N) | |
| ALLYL SUCROSE (UNII: VI3D59RW0U) | |
| HYDROGENATED SOYBEAN OIL (UNII: A2M91M918C) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|----------|
| Color | red | Score | no score |
| Shape | ROUND | Size | 18mm |
| Flavor | CHERRY | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0904-6255-49 | 18 in 1 CARTON | 12/28/2012 | |
| 1 | | 18 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 | M013 | 12/28/2012 | |

Labeler - Major Pharmaceuticals (191427277)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------|---------|-----------|------------------------|
| Bestco, Inc. | | 002149136 | manufacture(0904-6255) |

Revised: 11/2023

Major Pharmaceuticals