

**CHLORASEPTIC- menthol and benzocaine lozenge**  
**Prestige Brands Holdings, Inc.**

*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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**Chloraseptic Cherry Lozenge**

**Drug Facts**

**Active ingredients (in each lozenge)**

Benzocaine 6 mg

Menthol 10 mg

**Purpose**

Oral pain reliever

Oral pain reliever

**Uses**

Temporarily relieves occasional minor irritation, pain, sore throat and sore mouth.

**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. If a skin reaction occurs, stop use and seek medical help right away.

**Sore Throat Warning** Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.

Do not use more than 2 days or give to children under 6 years of age unless directed by a doctor.

**Do not use**

- for teething
- in children under 6 years of age

**When using this product**

do not exceed recommended dosage.

**Stop use and ask a dentist or doctor 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 care professional before use.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

***Directions***

- **Adults and children 6 years and older:** Take 1 lozenge every 2 hours as needed. Allow lozenges to dissolve slowly in the mouth.
- **Children under 6 years:** Do not use.

***Other information***

- store between 15<sup>o</sup> - 30<sup>o</sup>C (59<sup>o</sup> - 86<sup>o</sup>F)
- protect from moisture
- check expiration date before using

***Inactive ingredients***

Corn syrup, FD&C red no. 40, flavor, glycerin, soy lecithin, sucrose, water

***Questions?***

**1-800-552-7932**

**PRINCIPAL DISPLAY PANEL**


Chloraseptic<sup>®</sup>

Menthol | Benzocaine Oral Pain Reliever Lozenges

Cherry | 18 lozenges



<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> (in each lozenge) <b>Purpose</b>          Benzocaine 6 mg .....Oral pain reliever          Menthol 10 mg .....Oral pain reliever</p>	<p><b>Drug Facts</b> (continued)</p> <p>headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or give to children under 6 years of age unless directed by a doctor.</p>
<p><b>Uses</b> Temporarily relieves occasional minor irritation, pain, sore throat and sore mouth.</p>	<p><b>Do not use</b> ■ for teething ■ in children under 6 years of age</p>
<p><b>Warnings</b></p> <p><b>Methemoglobinemia warning:</b> 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</p>	<p><b>When using this product</b> do not exceed recommended dosage.</p> <p><b>Stop use and ask a dentist or doctor if</b>          ■ sore mouth symptoms do not improve in 7 days          ■ irritation, pain or redness persists or worsens          ■ swelling, rash or fever develops</p>
<p><b>Allergy Alert:</b> Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics. If a skin reaction occurs, stop use and seek medical help right away.</p>	<p><b>If pregnant or breast-feeding,</b> ask a doctor before use.  <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p>
<p><b>Sore Throat Warning:</b> Severe or persistent sore throat or sore throat accompanied by high fever, ►</p>	<p><b>Directions</b> ■ <b>Adults and children 6 years and older:</b> Take 1 lozenge every 2 hours as needed. Allow lozenges to dissolve slowly in the mouth. ■ <b>Children under 6 years:</b> Do not use.</p> <p><b>Other information</b> ■ Store between 15°-30°C (59°-86°F) ■ Protect from moisture ■ Check expiration date before using ▼</p>



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**Drug Facts** (continued)

**Inactive ingredients** corn syrup, FD&C red no. 40, flavor, glycerin, soy lecithin, sucrose, water

**Questions?** 1-800-552-7932

\*as lozenge dissolves

# CHLORASEPTIC

menthol and benzocaine lozenge

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67172-021
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CORN SYRUP</b> (UNII: 9G5L16BK6N)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>SUCROSE</b> (UNII: C151H8M554)	
<b>WATER</b> (UNII: 059QF0KOOR)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	4mm
<b>Flavor</b>	CHERRY	<b>Imprint Code</b>	C
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-021-18	1 in 1 CARTON	08/01/2010	
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 not final	part356	08/01/2010	

Revised: 5/2023

Prestige Brands Holdings, Inc.