

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.

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

Other information

- Store between 15°C - 30°C (59°F - 86°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 Chloraseptic.com

PRINCIPAL DISPLAY PANEL

Chloraseptic®

Menthol | Benzocaine Oral Pain Reliever Lozenges

Cherry | 18 lozenges



CHLORASEPTIC

menthol and benzocaine lozenge

Product Information

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

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	10 mg
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	6 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	4mm
Flavor	CHERRY	Imprint Code	C
Contains			

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	

Labeler - Prestige Brands Holdings, Inc. (159655021)

Revised: 7/2019

Prestige Brands Holdings, Inc.