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.

Chloraseptic Citrus 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 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^o 30^oC (59^o 86^oF)
- protect from moisture
- check expiration date before using

Inactive ingredients

corn syrup, FD&C red no. 40, FD&C yellow no. 6, flavor, glycerin, propylene glycol, soy lecithin, sucrose, water

Questions?

1-800-552-7932 or Chloraseptic.com

PRINCIPAL DISPLAY PANEL

Chloraseptic®

Menthol | Benzocaine Oral Pain Reliever Lozenges Citrus | 18 lozenges







CHLORASEPTIC

menthol and benzocaine lozenge

| Product Information | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67172-022 |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | |
|--|-------------------|----------|--|
| Ingredient Name | Basis of Strength | Strength | |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | 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) | | | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | | | |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) | | | | |
| SUCROSE (UNII: C151H8M554) | | | | |
| WATER (UNII: 059QF0KO0R) | | | | |

| Product Characteristics | | | |
|-------------------------|--------|--------------|----------|
| Color | orange | Score | no score |
| Shape | OVAL | Size | 4mm |
| Flavor | ORANGE | Imprint Code | С |
| Contains | | | |

| P | Packaging | | | |
|---|----------------------|--|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:67172-022- 18 | 3 in 1 CARTON | 08/01/2010 | |
| 1 | | 6 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 | |
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Revised: 5/2023 Prestige Brands Holdings, Inc.