

CHLORASEPTIC WARMING SORE THROAT- benzocaine lozenge
Prestige Brands Holdings, Inc.

Chloraseptic Green Tea Lozenges

[Chloraseptic© Warming Sore Throat Lozenges - Honey]

Drug Facts

Active ingredient

(in each lozenge)

Benzocaine 15 mg

Purpose

Oral Anesthetic/Analgesic

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 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 doctor before use.

Keep out of reach of children.

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

Directions

- **Adults and children 6 years of age and over:** 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 and 86°F)
- Protect from moisture.
- Check expiration date before using.
- Contains FD&C yellow no. 5 (tartrazine) as a color additive.

Inactive ingredients

corn syrup, FD&C yellow no. 5, flavor, glycerin, honey, propylene glycol, soy lecithin, sucrose, water

Questions?

1-800-552-7932 Chloraseptic.com

PRINCIPAL DISPLAY PANEL

**Chloraseptic® Warming Sore Throat Lozenges
Benzocaine Oral Anesthetic | Analgesic
18 lozenges | Honey Lemon**

<p>Drug Facts (continued)</p> <p>When using this product do not exceed recommended dosage.</p> <p>Do not use • for wetting • in children under 5 years of age.</p> <p>Stop use and ask a doctor or dentist if</p> <ul style="list-style-type: none"> • sore mouth symptoms do not improve in 7 days • irritation, pain or redness persists or worsens • swelling, rash or fever develops <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> • Adults and children 5 years of age and older: Take 1 lozenge every 2 hours as needed. Allow lozenges to dissolve slowly in the mouth. • Children under 5 years of age: Do not use. <p>Other information</p> <ul style="list-style-type: none"> • Store between 15°-30° C (59°-86° F) • Protect from moisture • Check expiration date before using • Contains FD&C yellow no. 5 (tartrazine) as a color additive 	<p>Drug Facts</p> <p>Active ingredient (in each lozenge): Benzocaine 15 mg Oral pain reliever</p> <p>Uses Temporarily relieves occasional minor irritation, pain, sore throat and sore mouth.</p> <p>Warnings</p> <p>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</p> <p>Allergy Alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, tetracaine, benzocaine or other "caine" anesthetics. If a skin reaction occurs, stop use and seek medical help right away.</p> <p>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 unless directed by a doctor.</p>
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Chloraseptic®
warming
SORE THROAT
LOZENGES HONEY LEMON

DOCTOR RECOMMENDED

Chloraseptic®
warming
SORE THROAT
LOZENGES

DOCTOR RECOMMENDED

Benzocaine Oral Pain Reliever Lozenges

■ **FAST ACTING**
■ **Numbs in Seconds***

HONEY LEMON | 18 lozenges

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Dist. by Medtech Products Inc., Tarrytown, NY 10591

Drug Facts (continued)

Inactive ingredients corn syrup, FD&C yellow no. 5, flavor, glycerin, honey, propylene glycol, soy lecithin, sucrose, water

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*as lozenge dissolves

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PRINCIPAL DISPLAY PANEL

Chloraseptic® Warming Sore Throat Lozenges
Benzocaine Oral Anesthetic | Analgesic
18 lozenges | Green Tea



CHLORASEPTIC WARMING SORE THROAT

benzocaine lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-018
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg

Inactive Ingredients

Ingredient Name	Strength
CORN SYRUP (UNII: 9G5L16BK6N)	
EPIGALLOCATECHIN GALLATE (UNII: BQM438CTEL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
HONEY (UNII: Y9H1V576FH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	green	Score	no score
Shape	OVAL	Size	4mm
Flavor	HONEY (Green Tea)	Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-018-02	1 in 1 CARTON	09/01/2012	
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	M022	09/01/2012	

CHLORASEPTIC WARMING SORE THROAT

benzocaine lozenge

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GLYCERIN (UNII: PDC6A3C0OX)	
HONEY (UNII: Y9H1V576FH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	yellow	Score	no score
Shape	OVAL	Size	4mm
Flavor	HONEY	Imprint Code	C
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67172-017-02	1 in 1 CARTON	01/01/2012	
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	M022	01/01/2012	

Labeler - Prestige Brands Holdings, Inc. (159655021)