# CHLORASEPTIC TOTAL SORE THROAT AND COUGH, SUGAR FREE- menthol and benzocaine and dextromethorphan hydrobromide 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 Sugar Free Lozenges

**Drug Facts** 

**Active Ingredients** 

(in each lozenge)

Benzocaine 6 mg

#### **Purpose**

Oral Anesthetic/Analgesic

**Active Ingredients** 

(in each lozenge)

Dextromethorphan HBr 5 mg

#### **Purpose**

Cough Suppressant

**Active Ingredients** 

(in each lozenge)

Menthol 10 mg

#### **Purpose**

Oral Anesthetic/Analgesic

#### Uses

Temporarily relieves

- occasional minor irritation, pain, sore throat and sore mouth
- cough due to minor throat and bronchial irritation as may occur with the common cold

#### Warnings

**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.

**Sore Throat Warning**: Severe or persistent sore throat or sore throat accompanied by high fever,

headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 6 years of age unless directed by a doctor.

#### Do not use

- this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health care professional before taking this product.
- this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor.

#### Ask a doctor before use if you have

- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- a cough accompanied by excessive phlegm (mucus)

#### 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
- cough persists for more than 1 week, tends to recur, or is accompanied by a high fever, rash, or persistent headache. These could be symptoms of a serious condition.

#### If pregnant or breast-feeding,

ask a health care professional 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 over 12 years of age:** 2 lozenges every 4 hours not to exceed 12 lozenges every 24 hours.
- **Children 6-12 years of age:** 1 lozenge every 4 hours not to exceed 6 lozenges every 24 hours.
- Children under 6 years of age: consult a doctor.

#### Other Information

- Store between 59°F and 86°F (15°C 30°C).
- Protect from moisture.
- Check expiration date before using.

## **Inactive Ingredients**

Acesulfame Potassium, FD&C Blue no. 1, FD&C Red no. 40, Flavor, Glycerine, Hydrogenated Starch Hydrolysate, Isomalt, Soy Lecithin, Sucralose, Water

#### Questions?

# 1-800-552-7932 Chloras eptic.com

#### PRINCIPAL DISPLAY PANEL

# Chloraseptic® Total Sugar Free SORE THROAT + COUGH Lozenges

Benzocaine / Menthol / Oral Anesthetic/Analgesic

Dextromethorphan HBr /Cough Suppressant

# Wild Cherry|15 lozenges



# CHLORASEPTIC TOTAL SORE THROAT AND COUGH, SUGAR FREE

menthol and benzocaine and dextromethorphan hydrobromide lozenge

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67172-015
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 mg	
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII:U3RS Y48 JW5)	BENZOCAINE	6 mg	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg	

Inactive Ingredients			
Ingredient Name	Strength		
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)			
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYDRO GENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)			
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			

Product Characteristics			
Color	RED	Score	2 pieces
Shape	OVAL	Size	4mm
Flavor	CHERRY	Imprint Code	С
Contains			

1	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67172-015-11	1 in 1 CARTON	08/01/2010	
1		15 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)

Establishment				
Name	Address	ID/FEI	Business Operations	
BestSweet, Inc.		0 0 2 1 4 9 1 3 6	MANUFACTURE(67172-015)	

Revised: 5/2017 Prestige Brands Holdings, Inc.