# TOPCARE SORE THROAT HONEY LEMON FLAVOR- benzocaine, menthol lozenge Topco Associates LLC

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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## **TopCare Honey Lemon Sore Throat Lozenges**

#### TopCare Sore Throat Honey Lemon Flavor

Active ingredients (in each lozenge)	Purpose
Benzocaine 15 mg	Oral anesthetic
Menthol 2.6 mg	Oral anesthetic

#### Uses

temporarily relieves these symptoms:

- occasional minor irritation, pain, sore mouth and sore throat
- pain associated with canker sores

#### Warnings

Allergy Alert: Do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine, or any other "caine" anesthetics.

Sore throat warning:

Severe or persistent sore throat or sore throat accompanied by high fever, headache, rash, nausea, and vomiting may be serious. Consult a dentist or doctor right away. Do not use more than 2 days or administer to children under 5 years of age unless directed by a doctor.

#### Stop Use and ask a doctor if

- sore throat is severe or irritation, pain or redness persists or worsens
- sore mouth symptom do not improve in 7 days

**If pregnant or breast-feeding,** ask a health professional before use.

### Keep this and all drugs out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

#### **Directions**

- adults and children 5 years of age and older: allow 1 lozenge to dissolve slowly in the mouth. May be repeated every 2 hours as needed or as directed by a doctor or dentist.
- children under 5 years: ask a doctor

#### Other information

- store at room temperature
- protect from moisture

## **Inactive ingredients**

glucose syrup, honey, N A Flavoring, propylene glycol, sucrose, water, and FD C yellow 5 (tartrazine), Soybean oil and corn starch used as processing aids.

#### Questions or comments?

1-888-423-0139

## TopCare Sore Throat Lozenges Honey Lemon Flavor 18 Count (36800-812-18)

TopCare

**FAST-ACTING RELIEF** 

Sore Throat

Lozenges

**MENTHOL • BENZOCAINE** 

ORAL ANESTHETIC

• Fast, soothing, temporary

relief of minor sore throat

pain and Irritation

Honey Lemon Flavor

COMPARE TO CEPACOL

active ingredients

18 LOZENGES

**DISTRIBUTED BY** 

TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

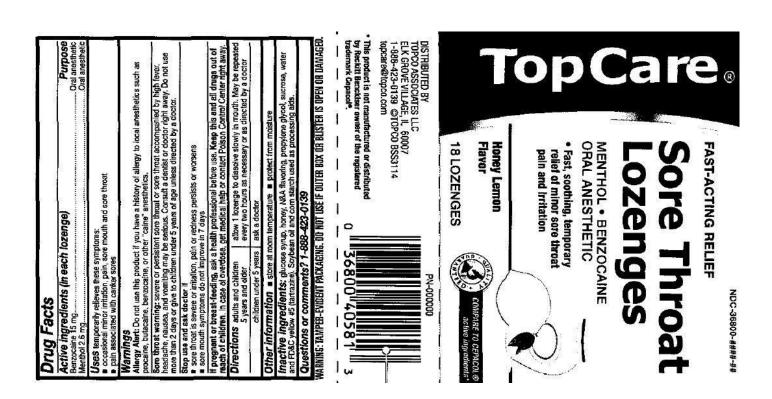
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## TOPCARE SORE THROAT HONEY LEMON FLAVOR

benzocaine, menthol lozenge

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-812	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII: U3RS Y48 JW5)	BENZOCAINE	15 mg		
MENTHOL (UNII: L7T10 EIP3A) (MENTHOL - UNII:L7T10 EIP3A)	MENTHOL	2.6 mg		

Inactive Ingredients					
Ingredient Name	Strength				
CORN SYRUP (UNII: 9G5L16BK6N)					
HO NEY (UNII: Y9H1V576FH)					
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)					
SUCROSE (UNII: C151H8M554)					
WATER (UNII: 059QF0KO0R)					
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)					
SOYBEAN OIL (UNII: 241ATL177A)					
STARCH, CORN (UNII: O8232NY3SJ)					

Product Characteristics			
Color	yello w	Score	no score
Shape	ROUND	Size	23mm

Flavor	HONEY, LEMON	Imprint C	Code		В
Contains					
Dackaging					
Packaging					
# Item Code	Package Description	Marketin	g Start Date	Ma	rketing End Date
1 NDC:36800-812-18	18 in 1 CARTON				
Marketing Information					
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End Date
OTC monograph not final	part356		02/25/2014		

## Labeler - Topco Associates LLC (006935977)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bestco, Inc.		002149136	manufacture(36800-812)	

Revised: 2/2014 Topco Associates LLC