

TOPCARE SORE THROAT CHERRY 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.

TopCare Cherry Sore Throat

TopCare Sore Throat Cherry Flavor

<i>Active ingredients (in each lozenge)</i>	<i>Purpose</i>
Benzocaine 15 mg	Oral anesthetic
Menthol 3.6 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

FD C Red 40, glucose syrup, N A Flavoring, propylene glycol, sucrose, and water. Soybean oil and corn starch used as processing aids.

Questions or comments?

1-888-423-0139

TopCare Sore Throat Lozenges Cherry Flavor 18 Count (36800-813-18)

TopCare

FAST-ACTING RELIEF

Sore Throat

Lozenges

MENTHOL • BENZOCAINE

ORAL ANESTHETIC

• Fast, soothing, temporary
relief of minor sore throat
pain and Irritation

Cherry Flavor

COMPARE TO CEPACOL

active ingredients

18 LOZENGES

DISTRIBUTED BY

TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

1-888-423-0139 ©TOPCO BSS3114

topcare@topco.com

This product is not manufactured or distributed
by Reckitt Benckiser owner of the registered
trademark Cepacol.

Drug Facts

Active ingredients (in each lozenge)
Benzocaine 15 mg
Menthol 3.6 mg

Purpose
Oral anesthetic
Oral anesthetic

Uses temporarily relieves these symptoms:
 ■ occasional minor irritation, pain, sore mouth and sore throat
 ■ pain associated with cancer 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 other "caine" anesthetics.
Sore throat warnings: severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a dentist or doctor right away. Do not use more than 2 days or give to children under 5 years of age unless directed by a doctor.
Stop use and ask doctor if:
 ■ sore throat is severe or initiation, pain or redness persists or worsens
 ■ sore mouth symptoms do not improve in 7 days

Directions adults and children 5 years and older
 ■ allow 1 lozenge to dissolve slowly in mouth. May be repeated every two hours as necessary or as directed by a doctor
 children under 5 years ■ ask a doctor

Other information ■ store at room temperature
 ■ protect from moisture

Inactive ingredients: FD&C Red #40, glucose syrup, NEA flavoring, propylene glycol, sucrose, and water. Soybean oil and corn starch used as processing aids

Questions or comments? 1-888-423-0139

WARNING: TAMPER-EVIDENT PACKAGING. DO NOT USE IF OUTER BOX OR BUSTER IS OPEN OR DAMAGED.

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TopCare®

FAST-ACTING RELIEF

Sore Throat Lozenges

MENTHOL • BENZOCAINE
ORAL ANESTHETIC

• Fast, soothing, temporary relief of minor sore throat pain and irritation

Cherry Flavor

18 LOZENGES

COMPARE TO CEFACOL® ACTIVE INGREDIENTS

NDC-36800-###-##

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TOPCARE SORE THROAT CHERRY FLAVOR

benzocaine, menthol lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-813
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	15 mg
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	3.6 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
CORN SYRUP (UNII: 9G5L16BK6N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0K00R)	
SOYBEAN OIL (UNII: 241ATL177A)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	23mm

Flavor	CHERRY	Imprint Code	B	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-813-18	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(36800-813)

Revised: 2/2014

Topco Associates LLC