

TOPCARE MAXIMUM STRENGTH- benzocaine liquid
Topco Associates LLC

5820344 Top Care Oral Pain Relief Liquid

Drug Facts

Active ingredient

Benzocaine 20.0% (w/w)

Purpose

Oral anesthetic

Uses

Temporarily relieves pain associated with the following mouth and gum irritations:

- toothache
- sore gums
- canker sores
- braces
- minor dental procedures

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

When using this product

- avoid contact with eyes
- do not exceed recommended dosage
- do not use for more than 7 days unless directed by a dentist or doctor

Stop use and ask doctor or dentist if

- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash or fever develops

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- **Adults and children 2 years of age and older:**
- apply to affected area using applicator tip
- use up to 4 times daily or as directed by a dentist or doctor
- children under 12 years of age should be supervised in the use of this product
- **children under 2 years of age:** consult a dentist or doctor

Other information

- do not use if package has been opened
- store at 20 - 25°C (68-77°F)

Inactive ingredients Benzyl Alcohol, D&C Yellow no. 10, FD&C Blue no. 1, FD&C Red no. 40, Methylparaben, Natural and Artificial Flavor, Polyethylene Glycol, Propylene Glycol, Sodium Saccharin, Water

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

QUESTIONS?

1-888-423-0139

topcare@topco.com

MADE IN CANADA



TOPCARE MAXIMUM STRENGTH			
benzocaine liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-443
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	20 g in 100 g
Inactive Ingredients			
Ingredient Name			Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
SACCHARIN SODIUM (UNII: SB8ZUX40TY)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
METHYLPARABEN (UNII: A2I8C7HI9T)			

BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	red (dark orange/red to sl brown)	Score	
Shape		Size	
Flavor	MINT (N&A Mint Flavor 619179)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-443-58	1 in 1 BLISTER PACK	10/01/2014	
1		14.17 g in 1 BOTTLE, WTH APPLICATOR; 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	10/01/2014	

Labeler - Topco Associates LLC (006935977)

Registrant - Lornamead Inc. (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
HK KOLMAR CANADA, INC		243501959	manufacture(36800-443) , pack(36800-443)

Revised: 3/2024

Topco Associates LLC