

TOPCARE ORAL PAIN RELIEF MAXIMUM STRENGTH- benzocaine gel
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.

5820342 TopCare Max Str Oral Pain Relief Gel

Drug Facts

Active ingredient

Benzocaine 20%

Purpose

Oral Pain Reliever

Use

- for the temporary relief of pain due to toothaches

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

Do not use

- more than directed
- for more than 7 days unless told to do so by a dentist or doctor
- for teething
- in children under 2 years of age

Stop use and ask a doctor if

- swelling, rash, fever develops
- irritation, pain or redness persists or worsens
- symptoms do not improve in 7 days
- allergic reaction occurs

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

Directions

- cut open tip of tube on scoremark
- **adults and children 2 years of age and older:** apply a small amount of product to the cavity and around the the gum surrounding the teeth. 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:** do not use

Other information

- do not use if tip is cut prior to opening
- this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted
- do not use continuously

Inactive ingredients flavor, polyethylene glycol, sodium saccharin, sorbic acid

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60057

QUESTIONS" 1-888-423-0139

topcare@topco.com www.topcarebrand.com



TOPCARE ORAL PAIN RELIEF MAXIMUM STRENGTH
benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-512
Route of Administration	TOPICAL		

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, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-512-29	1 in 1 CARTON	03/05/2019	
1		14 g in 1 TUBE; 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	03/05/2019	

Labeler - Topco Associates LLC (006935977)**Registrant** - Lornamead Inc. (080046418)**Establishment**

Name	Address	ID/FEI	Business Operations
Lornamead Inc.		080046418	manufacture(36800-512)