

**TOPCARE ORAL PAIN RELIEF MAXIMUM STRENGTH- benzocaine gel**  
**Topco Associates LLC**

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**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

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## 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
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBIC ACID</b> (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 Drug	M022	03/05/2019	

**Labeler** - Topco Associates LLC (006935977)**Registrant** - Lornamead Products (119559733)**Establishment**

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

Revised: 8/2025

Topco Associates LLC