

**TOPCO 4X MEDICATED TOOTHACHE AND GUM GEL- benzocaine gel  
TopCare**

*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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**5820620 4x Med Gel Topco**

Benzalkonium chloride

Benzocaine

Menthol

Zinc chloride

Oral antiseptic

Oral pain reliever

Oral pain reliever

Oral astringent

for the temporary relief of pain due to toothaches \* to help protect against infection of minor oral irritation

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 or 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.

cut open tip of tube on score mark \* adults and children 2 years of age and older: apply a small amount of product to the cavity and around 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

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 \* this formula will stay in place for extended duration of relief \* avoid using

toothpaste or drinking soft drinks or fruit juices for at least one hour after applying ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid



## TOPCO 4X MEDICATED TOOTHACHE AND GUM GEL

benzocaine gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-624
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZOCAINE</b> (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.5 g in 100 g
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBIC ACID (UNII: X045WJ989B)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

## Product Characteristics

Color	blue (Blue to Blue-Green)	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-624-49	1 in 1 CARTON	11/18/2020	
1		7 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	11/18/2020	

**Labeler** - TopCare (006935977)

**Registrant** - Lornamead (080046418)

## Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(36800-624) , pack(36800-624)