

SEVERE TRIPLE MEDICATED GEL- benzocaine gel

Topco

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 3x Medicated OP Gel

Benzocaine 20%

Menthol 0.5%

Zinc Chloride 0.15%

Oral pain reliever

Oral pain reliever

Astringent

for the temporary relief of oral pain due to minor irritation or injury of the mouth and gums

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 that 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 * allergice 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 between 2 and 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

blue 1, cellulose gum, gelatin, methyl salicylate, mineral oil, pectin, petrolatum, polyethylene glycol, sodium saccharin



LORNAMEAD
1.031 X 1.031 X 3.500 - PRINTSIDE
SBS S170274 - 3/9/17



<p>TOPCO ASSOCIATES LLC Creative Services 150 Northwest Point Boulevard Elk Grove Village, IL 60007-1015 phone: 847.676.3030</p>	<p>PROGRAM: Adobe Illustrator C56</p> <p>TOPCO PID: 361654</p> <p>BRAND: TopCare</p> <p>ITEM DESCRIPTION: TR_OralPainReliefSevereTripleMed_35oz_Crt</p> <p>CONSUMER UPC: 0-36800-46254-0</p> <p>SUPPLIER: Lornamead INC</p> <p>QR CODE SIZE: Small 5D</p>	<p>PROGRAM: Adobe Photoshop C56</p> <table border="1"> <thead> <tr> <th>DATE</th> <th>COMMENTS / CHANGES</th> </tr> </thead> <tbody> <tr> <td>4.3.16</td> <td>design - kfw, hw</td> </tr> <tr> <td>4.3.16</td> <td>production - gd</td> </tr> </tbody> </table>	DATE	COMMENTS / CHANGES	4.3.16	design - kfw, hw	4.3.16	production - gd	<p>CONTENT & DIE INFORMATION: Adapt this layout to your exact printing and die specifications. Modify any copy necessary to match your product specifications and legal requirements. The supplier is solely responsible for the accuracy and legality of all packaging copy.</p> <p>COLOR USAGE: This design is set up for the colors listed in the Topco legend. If the layout is modified to change the specified colors in any way, TOPCO MUST GIVE APPROVAL PRIOR TO THAT CHANGE BEING IMPLEMENTED. Failure to do so may result in packaging being destroyed at the supplier's cost.</p> <p>COLOR MATCHING: Refer to the Pantone® Color Formula Guide or to the Pantone® Process Color System Guide for the colors specified in this layout. Do not use this printout for an exact color match.</p>
	DATE	COMMENTS / CHANGES							
4.3.16	design - kfw, hw								
4.3.16	production - gd								
<p>COLOR STATIONS</p>									

<p>LORNAMEAD, INC.</p>		<p>PROJECT INFO PRODUCTION NOTES</p>	
<p>DATE: MAY 23, 2019</p> <p>PROJECT: TOPCO SEVERE GEL CARTON</p> <p>ITEM #: 2821389R1</p> <p>DIELINE #: S170274</p> <p>SIZE: 1.031" X 1.031" X 3.500"</p> <p>FILE NAME: TOPCO_SEVERE_DEL_CTN.2502_2821389R1-0L.AI</p> <p>PRINTER: MODPAC</p> <p>NOTE(S):</p>	<p>APPROVALS</p> <p>CREATIVE _____</p> <p>MARKETING _____</p> <p>R&D _____</p> <p>QUALITY _____</p> <p>PURCHASING _____</p> <p>CEO _____</p>		
<p>NEW YORK OFFICE 1399 BROADWAY 17TH FLOOR NEW YORK, NY 10018 TORAWANDA OFFICE 175 COOPER AVENUE TORAWANDA, NEW YORK 14150</p>			

SEVERE TRIPLE MEDICATED GEL

benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-389
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	0.55 g in 100 g
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.15 g in 100 g
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
PECTIN (UNII: 89NA02M4RX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

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:36800-389-99	1 in 1 CARTON	11/16/2020	
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	11/16/2020	

Labeler - Topco (006935977)

Registrant - Lornamead (080046418)

Establishment

Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(36800-389) , pack(36800-389)

Revised: 11/2020

Topco