

## **MG217COOLINGBURNSPRAY- lidocaine, benzalkonium chloride spray** **Wisconsin Pharmal Company**

*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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### **MG217 Cooling Burn Spray**

First aid to help prevent bacterial contamination or skin infections, and temporary relief of pain and itching associated with minor: cuts, scrapes, burns, sunburn, skin irritations.

### **Drug Facts**

#### **Active ingredients**

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Active ingredients

Benzalkonium Chloride 0.13%

Lidocaine HCl USP 4%

Purpose

First aid antiseptic

Pain reliever

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### **Uses**

First aid to help prevent bacterial contamination or skin infections, and temporary relief of pain and itching associated with minor: cuts, scrapes, burns, sunburn, skin irritations.

### **Warnings**

For external use only.

**Ask a doctor before use if you have** • deep puncture wounds • animal bites • serious burns

**When using this product** • do not use in or near the eyes • do not apply over large areas of the body or in large quantities • do not apply over raw surfaces or blistered areas • avoid prolonged storage above 40C° (104°F)

**Stop use and ask a doctor if** • condition worsens • symptoms persist for more than 7 days, or clear up and occur again within a few days.

**Keep out of reach of children.** if swallowed, get medical help or contact a Poison Control Center immediately.

### **Directions**

Adults and children 2 years and older: clean the affected area, apply a small amount on the area 1 to 3 times daily. • may be covered with a sterile bandage • if bandaged, let dry first.

## Other information

- Do not puncture or incinerate • contents under pressure

## Inactive ingredients

Aloe barbadensis leaf extract (Aloe vera), Camphor, Deionized water, Propylene glycol

## Questions or comments?

1-800-635-3696

## Principal Display Panel

<p><b>Drug Facts</b></p> <p><b>Active ingredients</b> <span style="float: right;"><b>Purpose</b></span>  Benzalkonium Chloride 0.13% ..... First aid antiseptic  Lidocaine HCl USP 4% ..... Pain reliever</p> <p><b>Uses</b> First aid to help prevent bacterial contamination or skin infections, and temporary relief of pain and itching associated with minor: ■ cuts ■ scrapes ■ burns ■ sunburn ■ skin irritations.</p> <p><b>Warnings</b>  <b>For external use only.</b>  Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns</p> <p>When using this product ■ do not use in or near the eyes ■ do not apply over large areas of the body or in large quantities ■ do not apply over raw surfaces or blistered areas ■ avoid prolonged storage above 40°C (104°F)</p> <p>Stop use and ask a doctor if ■ condition worsens ■ symptoms persist for more than 7 days, or clear up and occur again within a few days.</p> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p><b>Directions</b> Adults and children 2 years and older: clean the affected area, apply a small amount on the area 1 to 3 times daily. ■ may be covered with a sterile bandage ■ if bandaged, let dry first.</p> <p><b>Other information</b> ■ Do not puncture or incinerate ■ contents under pressure</p> <p><b>Inactive ingredients</b> Aloe barbadensis leaf extract (Aloe vera), Camphor, Deionized water, Propylene glycol</p> <p><b>Questions or comments?</b> 1-800-635-3696</p>	<div style="text-align: center;">  </div> <div style="background-color: #00a651; color: white; padding: 5px; text-align: center; font-weight: bold;">             topical pain relief • max strength         </div> <div style="background-color: #00a651; color: white; padding: 10px; text-align: center; font-size: 24pt; font-weight: bold;">             cooling burn spray         </div> <p style="text-align: center; font-weight: bold; color: #00a651;">             4% LIDOCAINE HCl              ALOE VERA  </p> <ul style="list-style-type: none"> <li>• cools skin &amp; restores moisture</li> <li>• soothing relief from:</li> </ul> <div style="display: flex; justify-content: space-around; align-items: center; text-align: center;"> <div style="text-align: center;">               Poison Ivy Oak, Sumac         </div> <div style="text-align: center;">               Insect Bites &amp; Stings         </div> <div style="text-align: center;">               Minor Burns &amp; Sunburn         </div> <div style="text-align: center;">               Minor Cuts &amp; Scrapes         </div> </div> <div style="text-align: center; margin-top: 20px;">  <p>non-sticky   sting-free</p> <p><b>NET WT 4 OZ (113 g)</b></p> </div>
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DOT2Q XXXX  


Manufactured by: Lake Consumer Products, Inc.  
 1 Pharmacal Way P.O. Box 198 Jackson, WI 53037 U.S.A.  
 1-800-635-3696 ©2019  
 MADE IN U.S.A. OF U.S. AND IMPORTED MATERIAL #B5024

## MG217 COOLING BURNS SPRAY

lidocaine, benzalkonium chloride spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68093-7319
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.013 g in 1 g
<b>LIDOCAINE</b> (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68093-7319-1	113 g in 1 CAN; Type 0: Not a Combination Product	04/17/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/17/2020	

**Labeler** - Wisconsin Pharmacal Company (800873986)

### Establishment

Name	Address	ID/FEI	Business Operations
Wisconsin Pharmacal Company		800873986	manufacture(68093-7319) , pack(68093-7319) , label(68093-7319)

Revised: 1/2022

Wisconsin Pharmacal Company