

## **LIDOCAINE- burn relief aerosol, spray**

**L. Perrigo 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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### **Good Sense Burn Relief Spray**

#### ***Active Ingredients***

Lidocaine 0.5%

#### ***Purpose***

External analgesic

#### ***Uses***

for the temporary relief of pain and itching associated with:

- sunburn
- minor burns
- minor cuts
- scrapes
- insect bites
- minor skin irritations

#### ***Warnings***

**For external use only.**

#### **Flammable:**

Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F

#### **Do not use**

in large quantities, particularly over raw surfaces or blistered areas.

#### **When using this product**

- do not get into eyes
- ask a doctor before using on children under 2 years of age

#### **Stop use and ask a doctor if**

- condition gets worse
- symptoms last more than 7 days or clears up and occurs again in a few days

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.

#### ***Directions***

- shake can well

- for adults and children 2 years and older, apply to affected area not more than 3 to 4 times daily
- for children under 2 years of age, ask a doctor
- to apply to face spray in palm of hand and gently apply

**Other information**

store between 20° and 25°C (68° and 77°F)

**Inactive ingredients**

aloe barbadensis gel, butane, carbomer, diazolidinyl urea, disodium cocoamphodipropionate, disodium EDTA, glycerine, methylparaben, propane, propylene glycol, propylparaben, tocopheryl acetate (vitamin E acetate), triethanolamine, simethicone, water

**Questions?**

Call 1-888-423-0139

**Principal Display Panel**

**GoodSense**

**Burn Relief Spray**

External analgesic

- Relieves pain and itching with Lidocaine
- Cools, Moisturizes And Soothes Sunburn
- Soothes Scrapes, Insect Bites & Minor Burns, Cuts & Skin Irritations

Net WT 4.5OZ (127g) □

<p><b>GOODSENSE®</b></p> <p><b>Burn Relief Spray</b></p> <p><b>Lidocaine 0.5% External Analgesic</b></p> <ul style="list-style-type: none"> <li>• Relieves pain and itching from sunburn, minor burns and insect bites</li> <li>• Cools, moisturizes and soothes sunburned skin</li> </ul> <p>Compare to the active ingredient of Solarcaine™*</p> <p><b>100% SATISFACTION GUARANTEED</b></p> <p>NET WT 4.5 OZ (127 g)</p> <p><small>*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Solarcaine®.</small></p>	<p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Lidocaine 0.5%.....</td> <td>External analgesic</td> </tr> </tbody> </table> <p><b>Uses</b> for temporary relief of pain and itching associated with:</p> <ul style="list-style-type: none"> <li>■ sunburn</li> <li>■ minor cuts</li> <li>■ scrapes</li> <li>■ minor burns</li> <li>■ insect bites</li> <li>■ minor skin irritations</li> </ul> <p><b>Warnings</b></p> <p><b>For external use only.</b></p> <p><b>Flammable</b> Use only as directed. Do not use while smoking or near heat or flame. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.</p> <p><b>Do not use</b> in large quantities, particularly over raw surfaces or blistered areas.</p> <p><b>When using this product</b></p> <ul style="list-style-type: none"> <li>■ do not get into eyes</li> <li>■ ask a doctor before using on children under 2 years of age</li> </ul> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ condition gets worse</li> <li>■ symptoms last more than 7 days or clear up and occur again in a few days</li> </ul> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.</p>	Active ingredient	Purpose	Lidocaine 0.5%.....	External analgesic	<p><b>Drug Facts (continued)</b></p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ shake can well</li> <li>■ for adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily</li> <li>■ for children under 2 years of age: consult a doctor</li> <li>■ to apply to face spray in palm of hand and gently apply</li> </ul> <p><b>Other information</b> store between 20° to 25°C (68° to 77°F)</p> <p><b>Inactive ingredients</b> aloe barbadensis leaf juice, butane, carbomer, diazolidinyl urea, disodium cocoamphodipropionate, disodium EDTA, glycerin, methylparaben, propane, propylene glycol, propylparaben, simethicone, tocopheryl acetate (vitamin E acetate), triethanolamine, water</p> <p><b>Questions? Call 1-866-964-0939</b></p>	<p style="writing-mode: vertical-rl; transform: rotate(180deg);">3/16 INCH OVERWRAP (NO TEXT)</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">50-0226S-01</p>
Active ingredient	Purpose						
Lidocaine 0.5%.....	External analgesic						



Distributed by:  
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Peachtree City, GA 30269  
www.valuelabels.com

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# LIDOCAINE

burn relief aerosol, spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0113-0135
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.64 g in 127 g

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTANE (UNII: 6LV4FOR43R)	
CARBOMER 934 (UNII: Z135WT9208)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPANE (UNII: T75W9911L6)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0113-0135-45	127 g in 1 CAN; Type 0: Not a Combination Product	01/03/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/03/2012	

**Labeler** - L. Perrigo Company (006013346)