

LIDOCAINE- burn relief aerosol, spray
Dolgenercorp, Inc. (DOLLAR GENERAL & REXALL)

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.

Rexall 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

Rexall
Burn Relief Spray
Lidocaine 0.5%
External Analgesic

- Relieves pain with lidocaine
- Cools, moisturizes, soothes sunburn
- Relieves insect bites & minor burns

NET WT 4.5 OZ (127 g)

NDC 00000-000-00

Since 1903
Rexall[®]

Burn Relief Spray
 LIDOCAINE 0.5%
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<p>Drug Facts</p> <p>Active ingredient Purpose Lidocaine 0.5%.....External analgesic</p> <p>Uses for temporary relief of pain and itching associated with: ■ sunburn ■ minor burns ■ minor cuts ■ insect bites ■ scrapes ■ minor skin irritations</p> <p>Warnings For external use only. Flammable: Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal. 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 clear up and occur again in a few days Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away</p>	<p>Drug Facts (continued)</p> <p>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</p> <p>Other information ■ store between 20° to 25°C (68° to 77°F)</p> <p>Inactive ingredients aloe barbadensis gel, butane, carbomer, diazolidinyl urea, disodium cocoamphodipropionate, disodium EDTA, glycerin, methylparaben, propane, propylene glycol, propylparaben, tocopheryl acetate (vitamin E acetate), triethanolamine, simethicone, water</p>
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50-022XX

3/16 INCH OVERWRAP (NO TEXT)

LIDOCAINE

burn relief aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:559 10-840
Route of Administration	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 940 (UNII: 4Q93RCW27E)	
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)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:559 10-840-45	127 g in 1 CAN; Type 0: Not a Combination Product	05/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/08/2017	

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)