# BURN RELIEF- lidocaine spray Solskyn Personal Care LLC

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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# GoodSense Burn Relief Spray 6oz

# **Active Ingredient**

Lidocaine 0.5%

# Purpose

External analgesic

#### Use

#### **INDICATIONS & USAGE SECTION**

Temporarily relieves pain and itching due to:

- Sunburn Minor burns
- Minor cuts Scrapes
- Insect bites Minor skin irritations

## **Dosage & Administration**

For the temporary relief of itching associated with minor skin irritations and rashes due to eczema, insect bites, and poison oak.

### Warnings

For external use only.

#### Do not use

Do not use in large quantities, particularly over raw surfaces or

blistered areas.

#### When using this product:

When using this product:

- Keep out of eyes.
- Use only as directed.
- Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°F.

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

Stop use and ask a doctor if:

- Condition gets worse
- Symptoms last more than 7 days
- Symptoms clear up and occur again in a few days

## Keep out of reach of children.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

#### **Directions**

- Shake well
- Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- Children under 2 years of age: ask a doctor
- To apply to face, spray on palm of hand and gently apply

## **Inactive Ingredients**

Water, Glycerin, Propanediol, Aloe Barbadensis Leaf Juice,
Carbomer, Tocopheryl Acetate, PEG-40 Hydrogenated Castor Oil,
Sodium Lauroyl Sarcosinate, Disodium EDTA, Phenoxyethanol,
Sodium Hydroxide

#### Questions or comments?

Distributed by: Geiss, Destin & Dunn, Inc. Peachtree City, GA 30269 www.valuelabels.com 800-715-3485

# **Principal Display Panel**

GoodSense
Burn Relief
Continuous Spray
Topical Analgesic

## With LidocainepROVIDES FAST RELIEF FROM:

- Sunburn
- Cuts & scrapes
- Insect bites,
- Minor burn & sunburn

## Compare and Save 100% Satisfaction Guaranteed

NET WT 6 OZ (170 g)



#### **BURN RELIEF**

lidocaine spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70281-640	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE (UNII: 98 PI200987) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE	0.5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
.ALPHATO COPHEROL ACETATE (UNII: 9E8 X80 D2L0)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
SODIUM LAURO YL SARCO SINATE (UNII: 632GS99618)		
CARBO XYPO LYMETHYLENE (UNII: 0 A5MM307FC)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
WATER (UNII: 059QF0KO0R)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPANEDIOL (UNII: 5965N8W85T)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:70281-640-06	170 g in 1 CAN; Type 0: Not a Combination Product	04/03/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/03/2019	

# **Labeler** - Solskyn Personal Care LLC (080010329)

Establishment				
Name	Address	ID/FEI	Business Operations	
KIK Piedmont LLC		078482780	manufacture(70281-640)	

Revised: 7/2019 Solskyn Personal Care LLC