GOODSENSE BURN RELIEF GEL- lidocaine hcl gel 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.

GoodSense Burn Relief Gel

Active Ingredients

Lidocaine 0.5%

Purpose

Topical Analgesic

Uses

• tempory relief of pain and itching associated with sunburn, minor burns, minor cuts, scrapes, minor skin irritations, and insect bites.

Dosage & Administration

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

When using this product

When using this product avoid contact with the eyes.

Stop use and ask a doctor

if condition worsens or if symptoms persist for more than 7 days or symptoms 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 right away.

Directions

- 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: do not use, ask a doctor.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Blue 5, Carbomer. Disodium, EDTA Glycerin, Menthol, Phenoxyethanol, Polysorbate 20, Propanediol, SD Alcohol (1.85% w/w). Sodium Hydroxide, Water, Yellow 5

Questions or Comments?

www.valuelabels.com

Principal Display Panel

GOODSENSE

BURN RELIEF

GEL

with

Lidocaine HCl

- Soothes & Relieves
- Restores Moisture
- Topical Analgesic Gel

with ALOE

Compare to active ingredients of

Solarcaine

100% satisfaction guaranteed

NET WT 8 OZ (226 g)

PKLA-41212-GSF1



BURN RELIEF GEL

with Lidocaine HCl

- Soothes & Relieves
- Restores Moisture
- Topical Analgesic Gel with ALOE

Compare to active ingredients of Solarcaine*



NET WT 8 OZ (226 g)

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Drug Facts

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Questions or comments? www.valuelabels.com

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

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*This product is not manufactured or distributed by Bayer, the owner of the registered trademark



GOODSENSE BURN RELIEF GEL

lidocaine hcl gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:70281-618

Route of Administration TOPICAL

Active Ingredient/Active Moiety

receive angle disease average		
Ingredient Name	Basis of Strength	Strength
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL (UNII: L7T10EIP3A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPANEDIOL (UNII: 5965N8W85T)	
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)	
BASIC YELLOW 5 (UNII: 07BP340B4T)	

ı	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:70281-618-26	226 g in 1 BOTTLE; Type 0: Not a Combination Product	0 1/0 4/20 19	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	0 1/0 4/20 19		

Labeler - Solskyn Personal Care LLC (080010329)

Establishment					
Name	Address	ID/FEI	Business Operations		
KIK Piedmont LLC		078482780	manufacture(70281-618)		

Revised: 6/2019 Solskyn Personal Care LLC