COOLING GEL- lidocaine hcl gel Walgreen 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.

WALG Cooling Gel 8OZ

Active ingredient

Lidocaine HCI 0.5%

Purpose

Topical Analgesic

Uses

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

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

When using this product

When using this product avoid contact with eyes.

Stop use and ask a doctor if

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.

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 1, Carbomer, Disodium EDTA, Glycerin, Menthol, Phenoxyethanol, Polysorbate 20, Propanediol, SD Alcohol (1.85% w/w), Sodium Hydroxide, Water, Yellow 5

Questions or comments?

Questions or comments? 1-800-925-4733

Principal Display Panel

Walgreens

Compare to Solarcaine

active ingredient

Cooling Gel

LIDOCAINE HCl 0.5% /

PAIN RELIEVER

SOOTHES & RELIEVES PAIN

RESTORES MOISTURE

• For minor cuts & scrapes,

insect bites, burns & sunburn

- Topical analgesic
- Contains aloe vera

NET WT 8OZ (226 g)

PKLA-41206-WGF1

Walgreens

Compare to Solarcaine® active ingredient^{||}

Cooling Gel

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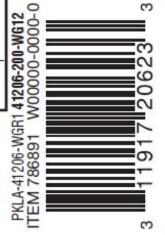
Propanediol, SD Alcohol (1.85% w/w), Sodium Hydroxide, Water, Yellow 5

Questions or comments? 1-800-925-4733

††This product is not manufactured or distributed by Bayer Consumer Holdings LLC, owner of the registered trademark SOLARCAINE®.

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ORG0119-F



COOLING GEL

lidocaine hcl gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-8897
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98 PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOXYPOLYMETHYLENE (UNII: 0 A5MM307FC)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
MENTHOL (UNII: L7T10 EIP3A)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
PHENO XYETHANO L (UNII: HIE492ZZ3T)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
PROPANEDIOL (UNII: 5965N8W85T)		
ALCOHOL (UNII: 3K9958V90M)		
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)		
WATER (UNII: 059QF0KO0R)		
BASIC YELLOW 5 (UNII: 07BP340B4T)		

l	Packaging			
# Item Code Package Description		Marketing Start Date	Marketing End Date	
ı	1 NDC:0363-8897-34 226 g in 1 BOTTLE; Type 0: Not a Combination Product		0 1/0 7/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	0 1/0 7/20 19	

Labeler - Walgreen Company (008965063)

Establishment			
Name	Address	ID/FEI	Business Operations
Kik Piedmont LLC		078482780	manufacture(0363-8897)

Revised: 7/2019 Walgreen Company