KROGER BURN RELIEF ALOE- lidocaine hydrochloride gel THE KROGER CO

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.

Drug Facts

Active ingredient

Lidocaine HCl 0.50%

Purpose

Topical Anesthetic

Uses

- temporary pain relief
- helps relieve and soothes pain from sunburn, minor burns, cuts, scrapes, skin irritations and insect bites.

Warnings

For external use only

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

When using this product

• avoid contact with eyes.

Stop use and ask a doctor if

- Conditions worsens or symptoms persists for more than 7 days.
- 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

Water, Propylene Glycol, Glycerin, Isopropyl Alcohol, Triethanolamine, Polysorbate 80, Carbomer, Aloe Barbadensis Leaf Juice Powder, Menthol, Disodium EDTA, Diazolidinyl Urea, Yellow 5, Blue 1.

Principal Display Panel

Kroger

QUALITY GUARANTEED Aloe Vera Burn Relief Gel with LIDOCAINE

Cools Sunburn Pain

NET WT 8 OZ (226 g)



KROGER BURN RELIEF ALOE

lidocaine hydrochloride gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-900	
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	0.5 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
TROLAMINE (UNII: 903K93S3TK)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)		
MENTHOL (UNII: L7T10 EIP3A)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:30142-900-16	226 g in 1 BOTTLE, PLASTIC			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	11/19/2012		

Labeler - THE KROGER CO (006999528)

Revised: 11/2012 THE KROGER CO