DUANE READE BURN RELIEF PAIN RELIEVING GEL- lidocaine hydrochloride gel DUANE READE INC.

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

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

Principal Display Panel

UNIQUELY NY DR_{TM} SINCE 1960 burn relief

pain relieving gel with Lidocaine NET WT 8 OZ (227 g)



DUANE READE BURN RELIEF PAIN RELIEVING GEL

lidocaine hydrochloride gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67732-406

Active Ingredient/Active Moiety						
Ingredient Name			Basis of	Basis of Strength		
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)			LIDOCAINE HYDROCHLORIDE		0.5 g in 100 g	
Inactive Ingredients						
Ingredient Name					Strength	
WATER (UNII: 059QF0KO0R)						
TROLAMINE (UNII: 903K93S3TK)						
ISOPROPYL ALCOHOL (UNII: ND2M416302)						
EDETATE DISODIUM (UNII: 7FLD91C86K)						
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: L7T10EIP3A)						
Packaging						
# Item Code	Package Description	Marketing Start Date		Market	Marketing End Date	
1 NDC:67732-406-16	226 g in 1 BOTTLE, PLASTIC					
Marketing Information						
Marketing Category	Application Number or Monograph Citation		Marketing Start	Date Mar	rketing End Date	
OTC monograph not final	part348		11/13/2012			

Labeler - DUANE READE INC. (011988995)

Revised: 10/2012

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