LEADER BURN RELIEF- lidocaine hydrochloride gel
Cardinal Health

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.

Leader Burn Relief Gel

Active ingredient

Lidocaine 1.0% (as Lidocaine HCl)

Purpose

External analgesic

Uses

temporarily relieves pain and itching due to:

- minor skin irritations
- sunburn
- minor burns
- scrapes
- minor cuts
- 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. If contact occurs, rinse with water to remove.

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.

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: ask a doctor.

Other information

may stain some fabrics

Inactive ingredients

aloe barbadensis leaf juice, triethanolamine, isoceteth-20, carbomer, tetrasodium EDTA, methylchloroisothiazolinone, methylisothiazolinone, water, benzophenone-4, blue 1.

Label

LEADER BURN RELIEF

lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0537
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
TROLAMINE (UNII: 9O3K93S3TK)	
ISOCETETH-20 (UNII: O020065R7Z)	
EDETATE SODIUM (UNII: MP1J8420LU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SULISOBENZONE (UNII: 1W6L629B4K)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0537-1	226 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/04/2019	

Labeler - Cardinal Health (063997360)

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