BURN RELIEF ALOE VERA GEL GNP- lidocaine hl gel Amerisource Bergen

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.

Burn Relief Aloe Gel [GNP]

Active ingredients

Purpose

Lidocaine Hydrochloride 0.5% External Analgesic

Uses

For the temporary relief of pain and itching due to • sunburn • minor burns • insect bites • minor cuts • scrapes • minor skin irritation

Warnings

For external use only.

When using this product: • avoid contact with eyes. Rinse with water if contact occurs.

Do not use in large quantities, particularly over raw surfaces or blistered areas. **Stop use and ask doctor if •** symptoms persist for more than 7 days, or 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 immediately.

Directions

- Adults and children 2 years and older: apply to affected area not more than 3 4 times a day.
- Children under 2 years of age: consult a physician.

Inactive ingredients

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

Questions or comments?



BURN RELIEF ALOE VERA GEL GNP

lidocaine hl gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:46122-654

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.5 g in 100 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALOE (UNII: V5VD430YW9)			
CARBOMER 940 (UNII: 4Q93RCW27E)			
DIAZOLIDINYL UREA (UNII: H5RIZ 3MPW4)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			

GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
MENTHOL (UNII: L7T10EIP3A)	
POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 903K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:46122-654-34	237 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/15/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/15/2021	

Labeler - Amerisource Bergen (007914906)

Registrant - Inspec Solutions LLC (081030372)

Establishment				
Name	Address	ID/FEI	Business Operations	
Inspec Solutions LLC		081030372	manufacture(46122-654)	

Revised: 1/2022 Amerisource Bergen