

SAFLY BURN- lidocaine hydrochloride cream
Nantong Health & Beyond Hygienic Products Inc.

43473-039 burn cream

Active ingredient

Benzalkonium Chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First Aid Antiseptic
Topical Analgesic

Uses

Temporary relief of pain associated with minor cuts, scrapes, and burns.
Helps protect against harmful bacteria.

Warnings

For external use only.

Do not use

- in eyes
- in large quantities
- over raw or blistered areas, or on deep puncture wounds, animal bites, or serious burns
- for more than one week unless directed by a doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center directly.

Directions

- clean affected area
- apply small amount not more than 3 times daily
- may be covered with a sterile bandage

Other Information

- store at room temperature
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

Aloe Barbadensis Leaf Juice, Cetearyl Alcohol, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl Stearate/PÉG-100 Stearate, Maltodextrin, Mineral Oil, Phenoxyethanol, Propylene Glycol, Purified Water, Stearic Acid, Triethanolamine.



SAFLY BURN		
lidocaine hydrochloride cream		
Product Information		
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:43473-039
Route of Administration	TOPICAL	
Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM -	BENZALKONIUM CHLORIDE	0.13 g

UNII:7N6JUD5X6Y)

BENZALKONIUM CHLORIDE

in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE (UNII: V5VD430YW9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
DISODIUM HEDTA (UNII: KME849MC7A)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MINERAL OIL (UNII: T5L8T28FGP)	
TRICLOSAN (UNII: 4NM5039Y5X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43473-039-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product	05/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	05/17/2024	

Labeler - Nantong Health & Beyond Hygienic Products Inc. (421280161)**Establishment**

Name	Address	ID/FEI	Business Operations
Nantong Health & Beyond Hygienic Products Inc.		421280161	manufacture(43473-039)

Revised: 5/2024

Nantong Health & Beyond Hygienic Products Inc.