

ROOSIN BURN- lidocaine hydrochloride cream
ROOSIN MEDICAL CO., LTD

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.

81552-002 Burn Cream

Active Ingredient

Banzalkonium Chloride 0.13%

Lidocaine Chloride 0.5%

Purpose

First Aid Antiseptic

External Analgesic

Antiseptic and antipyrotic

Use

First aid to help prevent infection and for temporary relief of pain and itching associated with minor cuts scrapes burns

WARNINGS

For external use only

Do not use

- In eyes
- Over large areas of the body
- For more than one week unless directed by a doctor
- If you are allergic to any of the ingredients
- On deep puncture wounds, animal bites, or serious burns

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away

Directions

Clean affected area

Apply a small amount 1-3 times daily

Children under 2: Consult doctor

Inactive ingredients

Petrolatum, Liquid Paraffin, Octadecanol, Glycerol, Stearic Acid, Purified Water, Aloe

60mm

30mm 30mm

70mm

Roosin®
Burn Cream

Antiseptic pain relief
with aloe

Drug Facts	
Active Ingredients	Purpose
Benzalkonium Chloride 0.13% ...	First aid antiseptic
Lidocaine HCL 0.5%	External Analgesic

Uses
First aid to help prevent infection and for the temporary relief of pain and itching associated with minor •cuts •scrapes •burns

Warnings
For external use only

NET WT 0.9g (1/32 OZ)

Drug Facts (continued)

Do not use

- In eyes
- Over large areas of the body
- In large quantities, particularly on raw or blistered areas
- If allergic to any ingredient
- On deep puncture wounds, animal bites, or serious burns

keep out of reach of children
If swallowed contact a Poison Control Center right away.

Directions
Adults
•Clean affected area
•Apply small amount 1-3times daily
Children under 2:Consult doctor

Inactive Ingredients

- Petrolatum •Liquid paraffin •Octadecanol
- Glycerol •Stearic Acid •Purified Water
- Aloe

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ROOSIN BURN

lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81552-002
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 - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
PETROLATUM (UNII: 4T6H12BN9U)	
PARAFFIN (UNII: I9O0E3H2ZE)	
OCTADECANOL (MIXTURE OF ISOMERS) (UNII: C6BPY2QY39)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCEROL FORMAL (UNII: 3L7GR2604E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81552-002-01	0.9 g in 1 TUBE; Type 0: Not a Combination Product	04/20/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/20/2021	

Labeler - ROOSIN MEDICAL CO., LTD (527587815)**Establishment**

Name	Address	ID/FEI	Business Operations
ROOSIN MEDICAL CO., LTD		527587815	manufacture(81552-002)

Revised: 12/2021

ROOSIN MEDICAL CO., LTD