# **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.

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### 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**

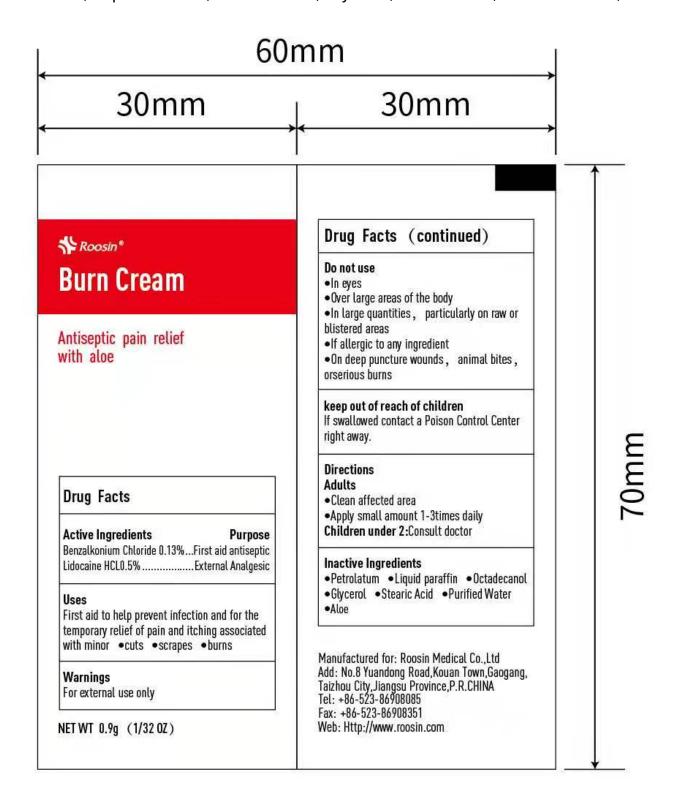
Clean affected area

Apply a small amount 1-3 times daily

Children under 2: Consult doctor

## Inactive ingredients

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



### **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	
<b>BENZALKONIUM CHLORIDE</b> (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: 1900E3H2ZE)			
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
	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	<b>Business Operations</b>		
ROOSIN MEDICAL CO., LTD		527587815	manufacture(81552-002)		

Revised: 12/2021 ROOSIN MEDICAL CO., LTD