

AFTER BURN- lidocaine hydrochloride gel

Adventure Ready Brands

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.

After Burn

Active Ingredient

Lidocaine Hydrochloride 2.50%

Purpose

Topical Analgesic

Uses

For the temporary relief of pain due to minor burns, sunburn, minor cuts, scrapes or minor skin irritations

Warnings

For external use only.

When using this product

- avoid contact with eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas
- do not use longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- condition worsens
- 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 right away.

If in eyes, flush with water for 15 minutes and call a doctor.

Directions

Clean affected area

Adults and Children 2 years and older apply small amount to affected area not more than 3 times daily

Children under 2 years consult a doctor.

Inactive Ingredients

Aloe Vera gel, benzalkonium chloride, carbomer 980, glycerol USP, herbal fragrance, menthol, polysorbate 20, propylene glycol, purified water, and sodium hydroxide (50%)

After Burn



AFTER BURN
lidocaine hydrochloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:90107-5120	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE HYDROCHLORIDE ANHYDROUS	25 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
CARBOMER HOMO POLYMER TYPE C (UNII: 4Q93RCW27E)				
GLYCERIN (UNII: PDC6A3C0OX)				
MENTHOL (UNII: L7T10EIP3A)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
WATER (UNII: 059QF0KO0R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:90107-5120-1	1 in 1 BOX	09/01/2020	
1		59 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:90107-5120-0	118 mL in 1 TUBE; Type 0: Not a Combination Product	09/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	09/01/2020		

Labeler - Adventure Ready Brands (064437304)

Registrant - Adventure Ready Brands (064437304)

Establishment

Name	Address	ID/FEI	Business Operations
Adventure Ready Brands		064437304	manufacture(90107-5120)