

FIRST AID BURN CREAM- lidocaine cream

Davemed Healthcare 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.

First Aid Burn Cream

Active Ingredients

Active Ingredient

Lidocaine HCL 0.5%

Benzalkonium Chloride 0.13%

Purpose

First aid antiseptic, external analgesic

Temporary relief of pain associated with minor burns

Uses

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

EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

If ingested, get medical help or contact a Poison Control Center right away.

DO NOT USE

DO NOT USE:

- in eyes
- in large quantities
- over raw blistered areas or on deep punctured wounds, animal bites or serious burns
- for more than one week

Directions

- Clean affected area
- apply small amount not more than 3 times daily
- maybe covered with a sterile bondage

Inactive ingredients

inactive ingredient

Other Information

Other Information

Store at room temperature

Principal Display Panel

B208

First Aid Burn Cream

Antiseptic Pain Relief With Aloe

ACTIVE INGREDIENTS

Benzalkonium Chloride 0.13%

Lidocaine HCL 0.5%

NET WT 0.9g (1/32 OZ)
NDC#

For temporary Relief of Pain Associated with Minor Burns

Drug Facts
Purpose: First aid antiseptic, 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
Do not use • in eyes • in large quantities • over raw blistered areas, or on deep puncture wounds, animal bites or serious burns • for more than one week
Keep out of reach of Children If ingested, contact a Poison Control Center right away.
Directions: • clean affected area • apply small amount not more than 3 times daily • Maybe covered with a sterile bandage
Other Information: store at room temperature <i>Manufactured in China for Davemed Healthcare Co., Ltd</i>

FIRST AID BURN CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70897-001
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	

GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYL PARAOXON (UNII: UE1A2XL95H)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIISOPROPYL PARAOXON (UNII: R90A2849YV)	
ALLANTOIN (UNII: 344S277G0Z)	
TRIETHANOLAMINE SULFATE (UNII: MV1V89M17O)	
STEARIC ACID D7 (UNII: T3B081197X)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR8914H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70897-001-01	0.9 g in 1 BAG; Type 0: Not a Combination Product	08/11/2016	
2	NDC:70897-001-02	42.5 g in 1 BAG; Type 0: Not a Combination Product	08/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/09/2016	

Labeler - Davemed Healthcare Co., Ltd (529128716)

Establishment

Name	Address	ID/FEI	Business Operations
Davemed Healthcare Co., Ltd		529128716	manufacture(70897-001)

Revised: 2/2020

Davemed Healthcare Co., Ltd