EASY CARE FIRST AID AFTERBURN- benzalkonium chloride, lidocaine cream Tender Corporation

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.

Easy Care First Aid AfterBurn Cream

Active Ingredients

Benzalkonium Chloride 0.13% Lidocaine HCL 0.5%

Purpose

First Aid Antiseptic

Topical Analgesic

Uses

- temporary relief of pain associated with minor burns
- helps protect against harmful bacteria

Warnings

For external use only.

Do not use

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

Stop use and ask a doctor if

- condition worsens
- if symptoms persist for more than 7 days or clears up and occurs again within a few days

Keep out of Reach of Children

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

Directions

- adults and children 2 years of age and older: clean the affected area; apply a small amount to the area 1-3 times daily; may be covered with a sterile bandage (let dry first).
- children under 2 years of age: consult a doctor

Inactive Ingredients

glycerin monostearate, glycerol, purified water, sodium dodecyl sulfate

Easy Care First Aid AfterBurn Cream

Serious Treatment for Burns

Responsibly Made in China for Tender Corporation Littleton, NH 03561 afterburnrelief.com

NDC 44224-0012

Net Wt. 1/32 oz (0.9 g)



After Burn' CREAM

Serious Treatment for Burns

Responsibly Made in China for:



Littleton, NH 03561 afterburnrelief.com

Drug Facts

Active ingredients Purpose

Benzalkonium- First Aid Antiseptic

Chloride 0.13%

Lidocaine- Topical Analgesic

hydrochloride 0.5%

Uses ■ temporary relief of pain associated with minor burns ■ helps protect against harmful bacteria

Drug Facts (continued)

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ART - 5020-0210-1

EASY CARE FIRST AID AFTERBURN

benzalkonium chloride, lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44224-0012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)			
GLYCERIN (UNII: PDC6 A3C0 OX)			
WATER (UNII: 059QF0KO0R)			

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:44224-0012-1	0.9 g in 1 PACKET; Type 0: Not a Combination Product	09/01/2019		
2	NDC:44224-0012-2	6 in 1 BOX	09/01/2019		
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product			
3	NDC:44224-0012-3	100 in 1 CARTON	09/01/2019		
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/01/2019		

Labeler - Tender Corporation (064437304)

Establishment				
Name	Address	ID/FEI	Business Operations	
GFA Production (Xiamen) Co., Ltd.		421256261	manufacture(44224-0012)	

Revised: 9/2019 Tender Corporation