

FIRST AID AND BURN- first aid and burn cream

B8 Sales, Inc.

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.

PIO Put it on®

First Aid & Burn Cream™

- For Temporary Relief of Pain Associated with Minor Burns
- Helps Protect Against Harmful Bacteria

25 Packets

Each Packet Net.Wt.0.9gm

Drug Facts

Active ingredients

Benzalkonium Chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First Aid Antiseptic

Topical Analgesic

Uses

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

Warnings

For 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

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

Stop use and ask a doctor if

- the condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Directions

Adults and children 2 years and over: clean affected area, apply small amount not more than 3 to 4 times

daily Children under 2 years: do not use, consult a doctor

Other information

- store at room temperature (do not freeze)
- do not use any opened or torn packets

Inactive ingredients

aloe vera, emulsifying wax, ethyl alcohol, methylparaben, mineral oil, paraffin, propylparaben, purified water, white petrolatum, white wax

Principal Display Panel

First Aid & Burn Cream – Carton Label

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FIRST AID AND BURN

first aid and burn cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50607-5700
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzalkonium Chloride (UNII: F5UM2KM3W7) (Benzalkonium - UNII:7N6JUD5X6Y)	Benzalkonium Chloride	1.3 mg in 1 g
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
aloe (UNII: V5VD430 YW9)	
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
petrolatum (UNII: 4T6HI2BN9U)	
white wax (UNII: 7G1J5DA97F)	

Product Characteristics

Color	white (white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50607-5700-1	25 in 1 BOX		
1		.9 g in 1 POUCH		
2	NDC:50607-5700-2	144 in 1 BOX		
2		.9 g in 1 POUCH		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333	05/01/2010	

Labeler - B8 Sales, Inc. (833208635)

