FIRST AID- benzalkonium chloride and lidocaine cream
Provision Medical

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.

Active ingredient (in each gram)

Benzalkonium Chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First Aid Antiseptic

Topical Analgesic

Uses

- temporary relief of pain associated with minor burns, cuts and scrapes
- helps protect against harmful bacteria

Warnings

For external use only

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

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
- may be covered with a sterile bandage.

Inactive Ingredients

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

Manufactured for:
Provision Medical Products
Palm Desert, CA 92211

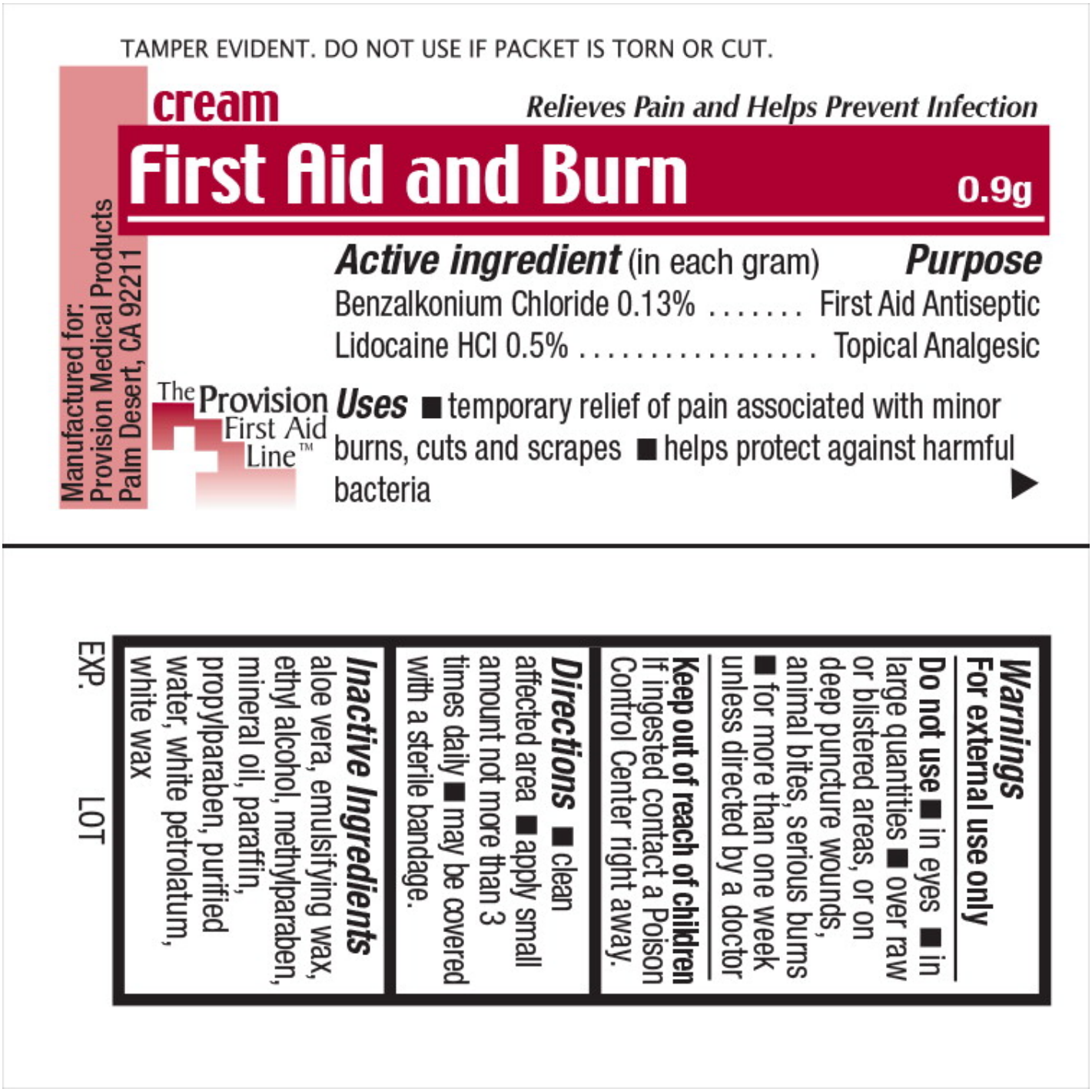
Principal Display Panel - Pouch Label

TAMPER EVIDENT. DO NOT USE IF PACKET IS TORN OR CUT.

cream ***Relieves Pain and Helps Prevent Infection***

First Aid and Burn 0.9g

The **Provision**
First Aid
Line™



FIRST AID
benzalkonium chloride and lidocaine cream
Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69103-3553
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 (UNII: 98PI200987) (lidocaine - UNII:98PI200987)	lidocaine	5.0 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
alcohol (UNII: 3K9958V90M)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
petrolatum (UNII: 4T6H12BN9U)	
white wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-3553-1	0.9 g in 1 POUCH; 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	12/02/2014	

Labeler - Provision Medical (036936831)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-3553)

Revised: 12/2014 Provision Medical