LIDOCAINE HYDROCHLORIDE- lidocaine hydrochloride gel
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.

Drug Facts

Active Ingredient

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 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
- children under 2: consult a doctor

Inactive Ingredients

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

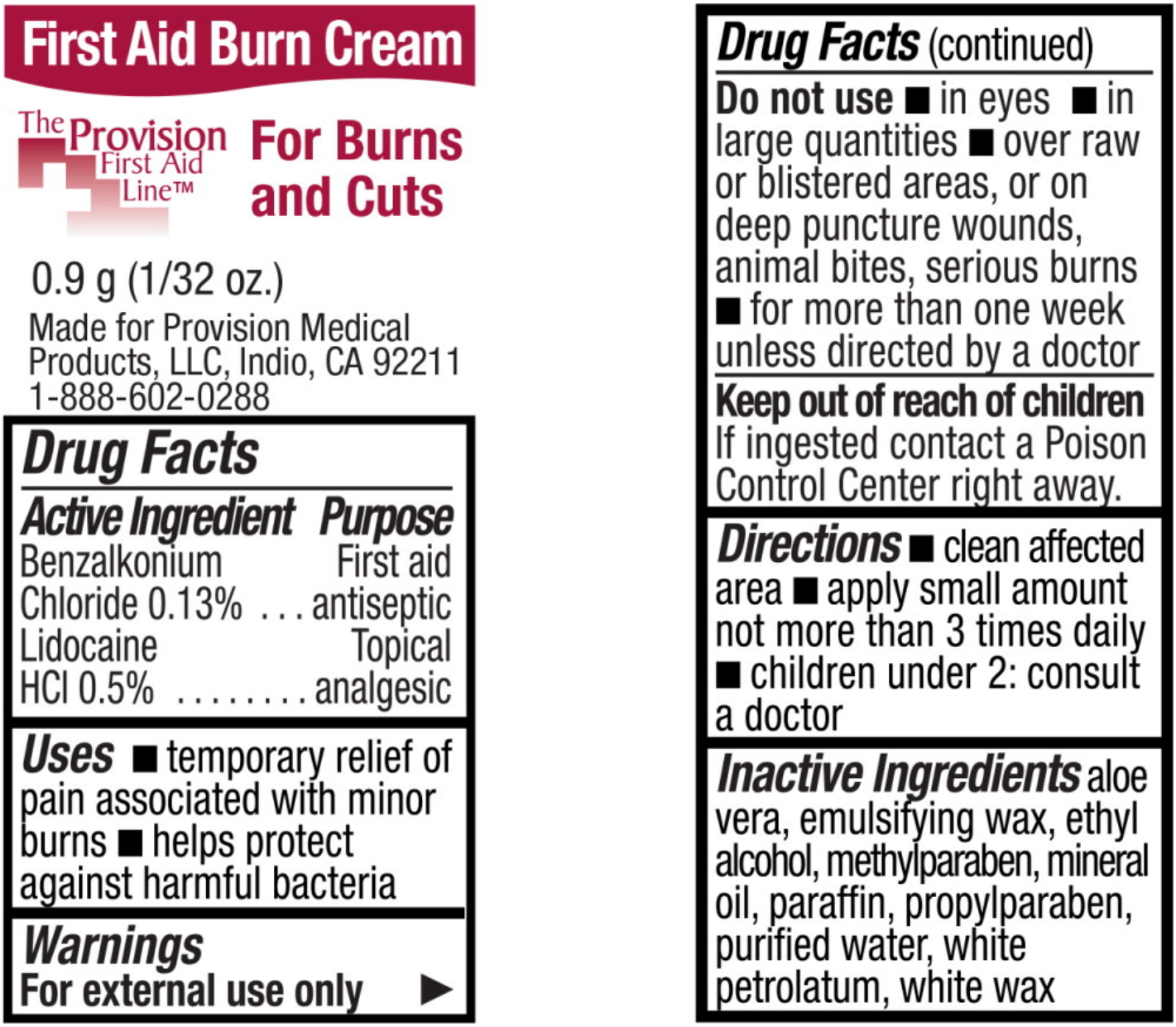
Principal Display Panel – 0.9 g Packet Label

First Aid Burn Cream

The **Provision**
First Aid
Line™

For Burns
and Cuts

0.9 g (1/32 oz.)



LIDOCAINE HYDROCHLORIDE

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69103-5000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Lidocaine Hydrochloride (UNII: V13007Z41A) (Lidocaine - UNII:98PI200987)	Lidocaine Hydrochloride Anhydrous	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY81Z83H0X)	
propylene glycol (UNII: 6DC9Q167V3)	
diazolidinyl urea (UNII: H5RIZ3MPW4)	
water (UNII: 059QF0KO0R)	
menthol (UNII: L7T10EIP3A)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69103-5000-0	0.9 g in 1 PACKET; Type 0: Not a Combination Product	07/25/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/25/2022	

Labeler - Provision Medical (036936831)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(69103-5000)

Revised: 11/2013 Provision Medical