ANTISEPTIC- benzalkonium chloride, lidocaine hydrochloride cream
Total Resources International

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 ingredients

Benzalkonium

Chloride 0.13% **w/w**

Lidocaine

HCI 0.5% **w/w**

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 – Pouch Label

BE SMART

GET PREPARED

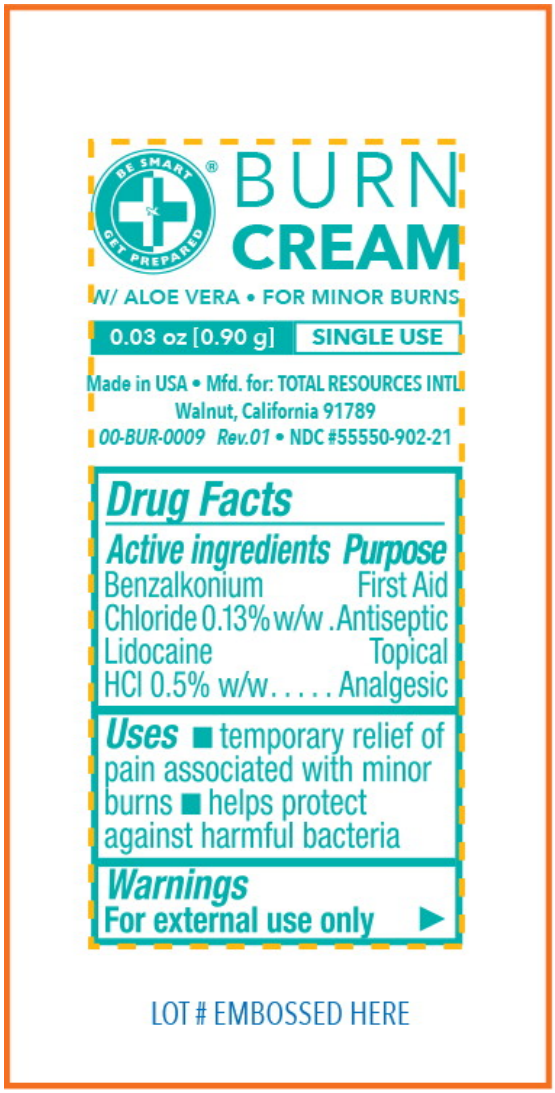
BURN
CREAM
W/ ALOE VERA • FOR MINOR BURNS

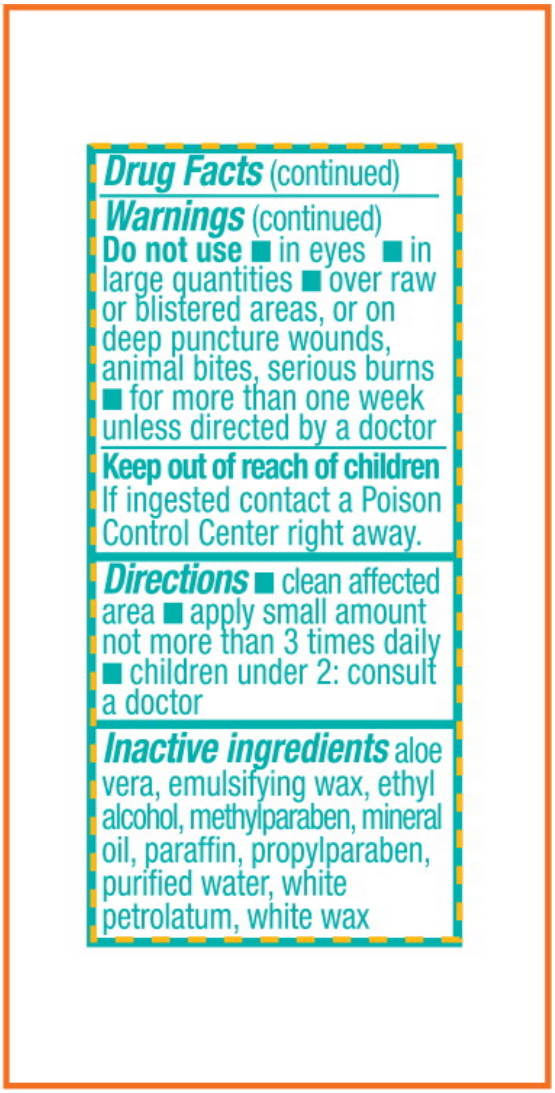
0.03 oz [0.90 g]

SINGLE USE

Made in USA • Mfd. for: TOTAL RESOURCES INTL.
Walnut, California 91789

***00-BUR-0009 Rev.01* • NDC #55550-902-21**





ANTISEPTIC

benzalkonium chloride, lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55550-902

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 anhydrous	5 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:55550-902-21	0.9 g in 1 POUCH; Type 0: Not a Combination Product	01/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/14/2020	

Labeler - Total Resources International (790160535)

Revised: 1/2020 Total Resources International