

FIRST AID BURN- benzalkonium chloride, lidocaine hydrochloride cream
Water-Jel Technologies

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.

First Aid Burn Cream

Active ingredients

Benzalkonium chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First Aid antiseptic

External analgesic

Uses

first aid to help prevent infection and for the temporary relief of pain and itching associated with

- minor cuts
- scrapes
- burns

Warnings

For external use only

Do not use

- in the eyes or apply over large areas of the body
- longer than 1 week unless directed by a doctor
- in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have

deep or puncture wounds, animal bites, or serious burns

When using this product

avoid contact with eyes

Stop use and ask a doctor if

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

Keep out of the 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 of this product on the area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: consult a doctor

Other information

- store at room temperature (do not freeze)
- tamper evident sealed packets
- do not use if packet is opened or torn
- you may report a serious reaction to this product to 800-275-3433

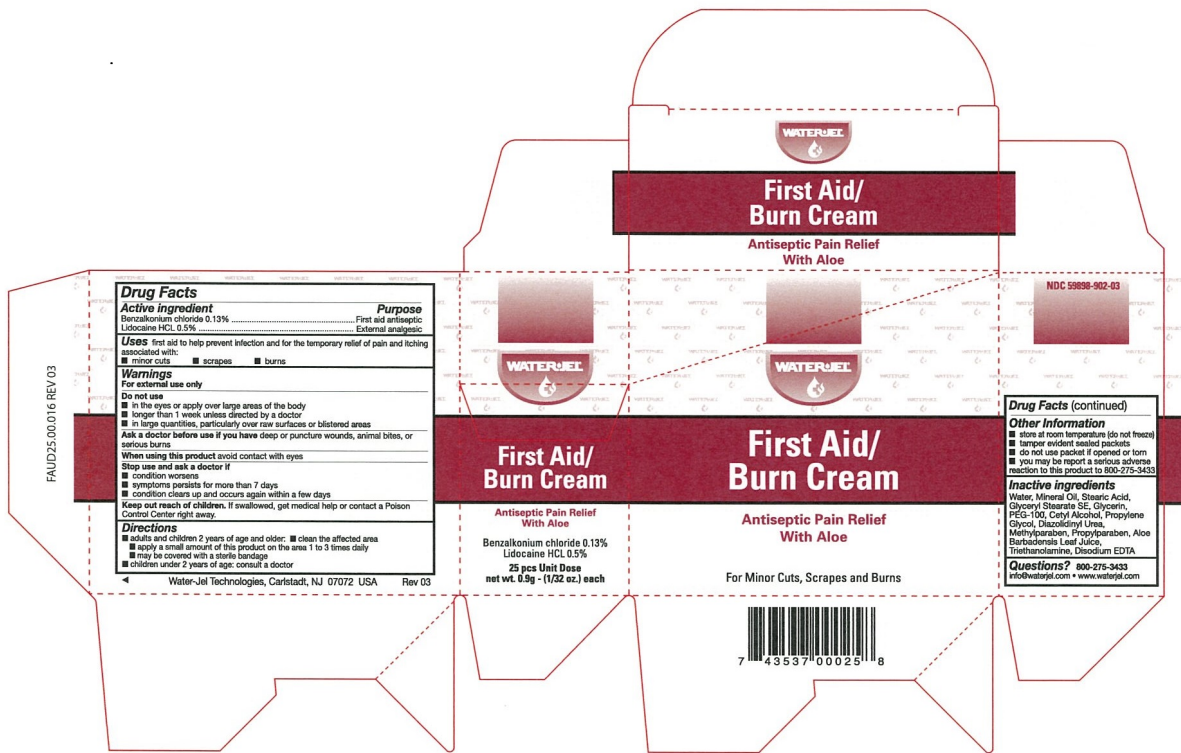
Inactive ingredients

water, mineral oil, stearic acid, glyceryl stearate se, glycerin, Peg-100, cetyl alcohol, propylene glycol, diazolidinyl urea, methylparaben, propylparaben, aloe barbadensis leaf juice, triethanolamine, disodium EDTA

Questions?

800-275-3433 info@waterjel.com www.waterjel.com

Principal Display Panel



FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59898-902
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59898-902-01	1728 in 1 CARTON	04/20/2010	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:59898-902-02	144 in 1 BOX, UNIT-DOSE	04/20/2010	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:59898-902-03	25 in 1 BOX, UNIT-DOSE	04/20/2010	
3		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:59898-902-36	0.9 g in 1 PACKET; Type 0: Not a Combination Product	04/20/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/20/2010	

Labeler - Water-Jel Technologies (155522589)

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(59898-902)