

BURN CREAM- benzalkonium chloride, lidocaine hci cream
Trifecta Pharmaceuticals USA LLC

Globe First Aid Burn Cream

Active Ingredient

Lidocaine HCL 0.5%

Purpose

Topical Analgesic

Benzalkonium Chloride 0.13%

Purpose

First Aid Antiseptic

Uses

Temporary Relief of pain associated with minor cuts, scrapes and 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, or serious burns
- for more than one week unless directed by a doctor

Directions

- Clean the affected area
- Apply a small amount not more than 3 times daily
- May be covered with a sterile bandage

Inactive Ingredients

Aloe barbadensis leaf juice, Cetyl alcohol, Diazolidinyl urea, Edetate disodium, glycerin, methylparaben, Mineral oil, Mono and di glycerides, PEG-100 stearate, propylene glycol, propylparaben, stearic acid, triethanolamine, water

Questions

Call: 1-888-296-9067

Storage Information

- Store in cool dry area 15° to 25°C (59° to 77°F).
- tamper evident sealed packets
- do not use any opened or torn packets

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Other Information

Distributed By:

Trifecta Pharmaceuticals USA®

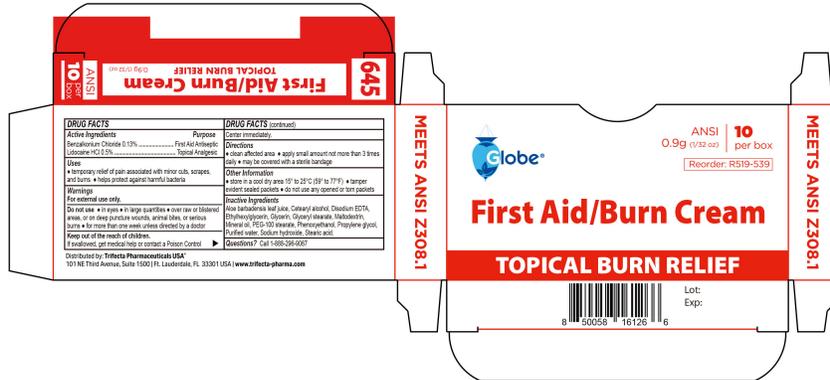
101 NE Third Ave. Ste 1500

Ft. Lauderdale, FL. 33301 USA

www.trifecta-pharma.com

Package Label

OUTSIDE BOX



INNER PACKET

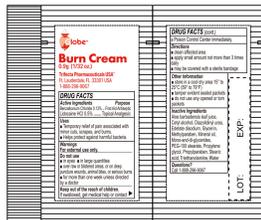


Package Label

OUTSIDE BOX



INNER PACKET



BURN CREAM

benzalkonium chloride, lidocaine hci cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-136
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.005 g in 1 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MINERAL OIL (UNII: T5L8T28FGP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-136-10	10 in 1 CARTON	10/23/2023	
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69396-136-25	25 in 1 CARTON	10/23/2023	
2		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	10/23/2023	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)