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®

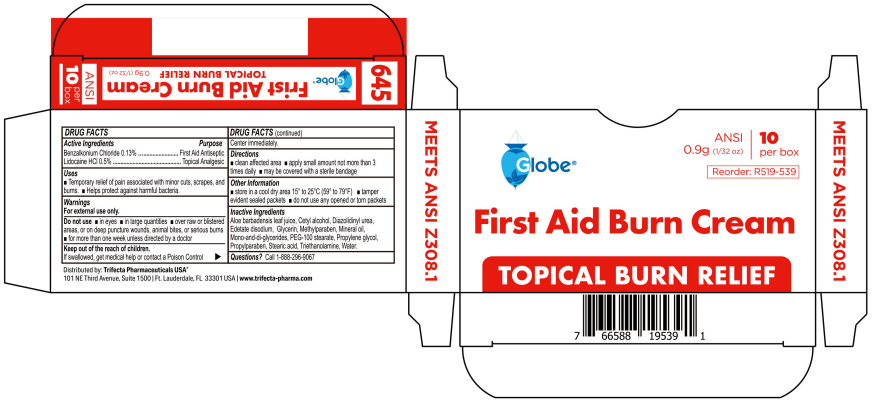
101 NE Third Ave. Ste 1500

Ft. Lauderdale, FL. 33301 USA

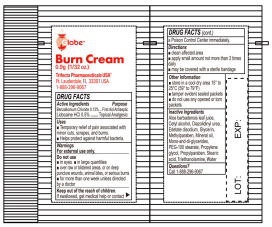
www.trifecta-pharma.com

Package Label

OUTSIDE BOX



INNER PACKET



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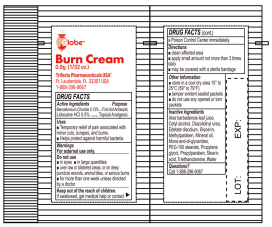

BURN CREAM

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**

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)

Revised: 10/2023 Trifecta Pharmaceuticals USA LLC