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

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.

Urgent 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, Cetearyl alcohol, Disodium EDTA, Ethylhexylglycerin, Glycerin, Glyceryl stearate/PEG-100 stearate, Maltodextrin, Mineral oil, Phenoxyethanol, Propylene glycol, purified water, stearic acid, Triethanolamine.

Questions

To reorder:

Call 1-760-642-2638

Storage Information

- Store in cool dry area 15° to 25°C (59° to 79°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

Manufactured for:

Urgent First Aid®

2603 Industry Street

Oceanside, CA. 92054 USA

www.UrgentFirstAid.com

Reorder # URG-400

OUTSIDE BOX

INNER PACKET

BURN CREAM

benzalkonium chloride, lidocaine hci cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69396-124
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
GLYCERYL STEARATE/PEG-100 STEARATE (UNII: RD25J5V947)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TROLAMINE (UNII: 9O3K93S3TK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-124-09	25 in 1 CARTON	03/02/2023	
1		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 not final	part348	03/02/2023	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)