MEDI-FIRST- benzalkonium chloride, lidocaine cream
Orazen Inc

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.

MEDI-FIRST PLUS
Burn cream with Lidocaine

Active ingredients

Benzalkonium Chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First aid antiseptic

Topical analgesic

Uses

- for the temporary relief of pain associated with minor burns
- helps protect against harmful bacteria

Warnings

For external use only.

Do not use

- in the 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

Stop use and ask a doctor if

- the condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If ingested, get medical help or contact a Poison Control Center right away.

Directions

- **Adults and children 2 years and over:** clean the affected area, apply a small amount not more than 3 to 4 times daily
- **Children under 2 years:** do not use, consult a doctor

(continued on next panel)

Other information

- store at room temperature (do not freeze)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

aloe barbadensis leaf juice, cetearyl alcohol,disodium EDTA, ethylhexylglycerin, glycerin, glyceryl stearate, mineral oil, maltodextrin, propylene glycol, purified water, PEG-100 stearate,phenoxyethanol, stearic acid, triethanolamine

Questions or comments?

800-634-7680

Package Label - Principal Display Panel

Burn Cream
with Lidocaine

Net Wt. 0.9 g (1/32 oz)

Active ingredient	***Purpose***
Benzalkonium Chloride 0.13%	First aid antiseptic
Lidocaine HCl 0.5%	Topical analgesic

Uses ■ temporary relief of pain associated with minor burns ■ helps protect against harmful bacteria

Store at room temperature • Tamper Evident Sealed Packet

Warnings **For external use only**

Do not use ■ in eyes ■ in large quantities ■ over raw surfaces 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, get medical help or contact a Poison Control Center right away.

Directions ■ clean affected area ■ apply a small amount not more than 3-4 times daily ■ children under 2 years: consult a doctor

Inactive ingredients aloe barbadensis leaf juice, cetearyl alcohol, disodium EDTA, ethylhexylglycerin, glycerin, glyceryl stearate, mineral oil, maltodextrin, propylene glycol, purified water, PEG-100 Stearate, phenoxyethanol,stearic acid, triethanolamine

Retain Carton for Complete Product Information

Mfd for Medique Products,
Fort Myers, FL 33967

MEDI-FIRST

benzalkonium chloride, lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71927-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 mg in 1 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
WATER (UNII: 059QF0KO0R)	

GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-019-03	25 in 1 BOX	02/20/2023	
1	NDC:71927-019-01	0.9 g in 1 POUCH; 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	02/20/2023	

Labeler - Orazen Inc (080916640)

Revised: 2/2023 Orazen Inc