

**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.*

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**MEDI-FIRST**  
**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**

Benzalkonium Chloride 0.13% .....First aid antiseptic  
Lidocaine HCl 0.5% ..... Topical analgesic

**Purpose**

**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

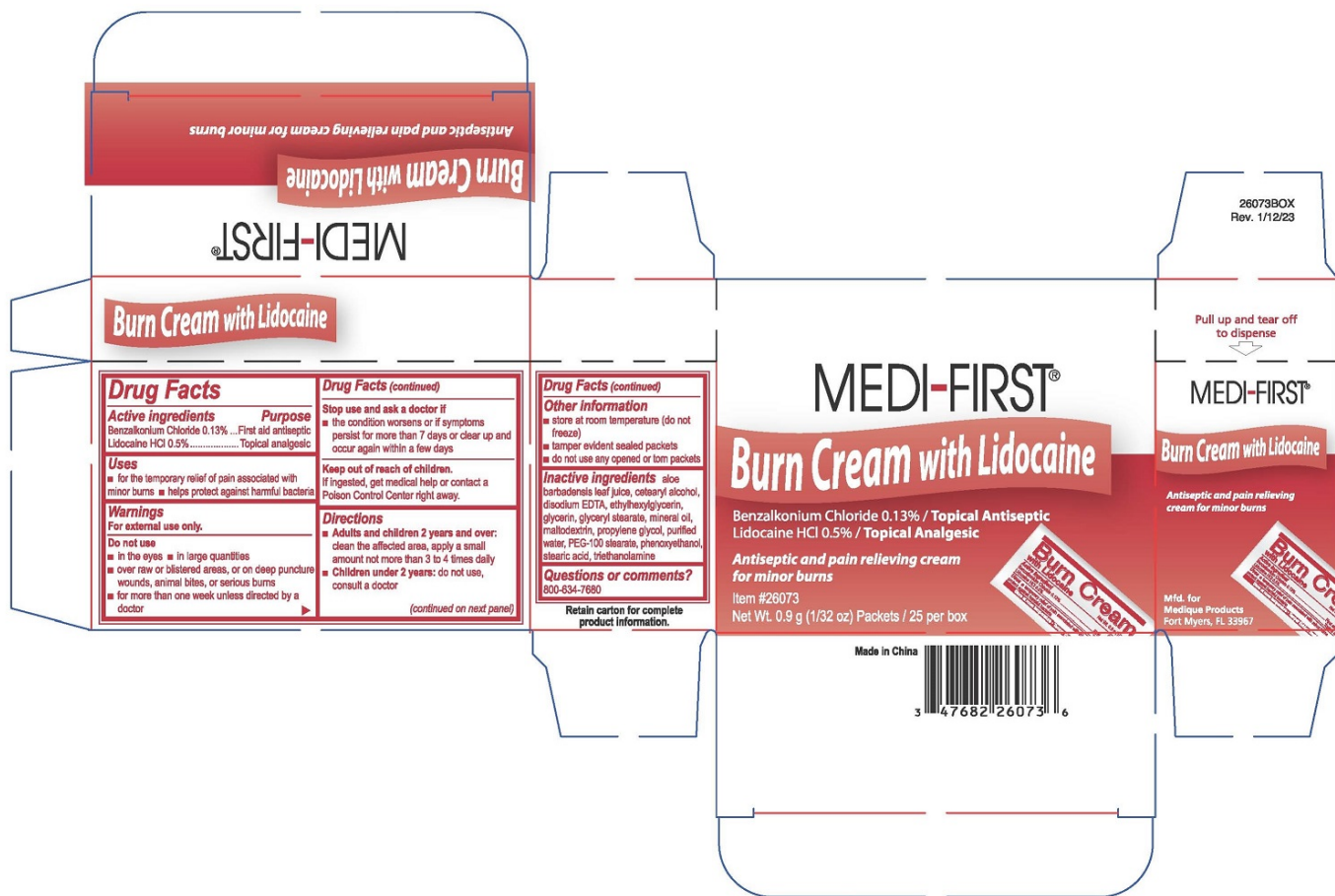
**Keep out of reach of children.** If ingested, get medical help or contact a Poison Control Center right away.

**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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71927-019
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>WATER</b> (UNII: 059QF0KO0R)	

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71927-019-02	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