BURN TREATMENT- benzalkonium chloride, lidocaine hydrochloride cream
CMC Group 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.

Burn Treatment

Drug Facts

Active ingredients

Benzalkonium chloride 0.13%

Lidocaine hydrochloride 0.5%

Purpose

First aid antiseptic

Pain relieving cream

Uses

- First aid to help prevent infection in minor cuts, scrapes, and burns.
- For the temporary relief of pain and itching associated with minor burns , minor cuts, and scrapes

Warnings

For external use only.

Do not use

• in the eyes • over large areas of the body • in large quantities • over raw surfaces or blistered areas • longer than 1 week unless directed by a doctor

Ask a doctor before use if you have

• deep or puncture wounds • animal bites • serious burns.

Stop use and ask a doctor if

• the condition persists or gets worse • symptoms persist for more than 7 days or clear up and occur again within a few days

Keep out of reah of children.

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

Directions

- Clean the affected area
- Adults and children 2 years of age and older: Apply a small amount of this product to affected area not more than 3 times daily
- Children under 2 years of age: consult a doctor
- May be covered with a sterile bandage

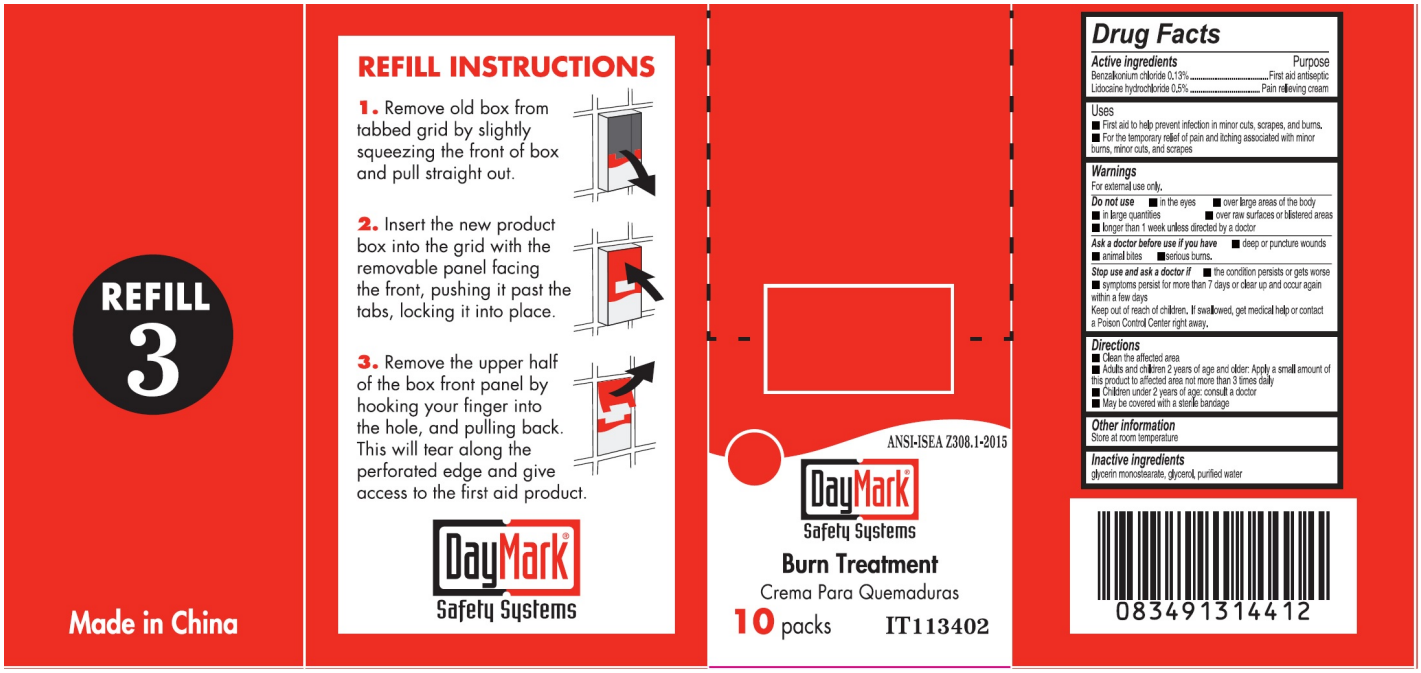
Other information

Store at room temperature

Inactive ingredients

glycerin monostearate, glycerol, purified water

Package Labeling:



BURN TREATMENT

benzalkonium chloride, lidocaine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49687-0014
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49687-0014-0	10 in 1 KIT	08/06/2016	
1		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	part333A	08/06/2016	

Labeler - CMC Group Inc. (005583328)

Revised: 1/2020 CMC Group Inc.