

REFILL 3- benzalkonium chloride, lidocaine hydrochloride cream
CMC Group Inc.

Refill 3

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 reach 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

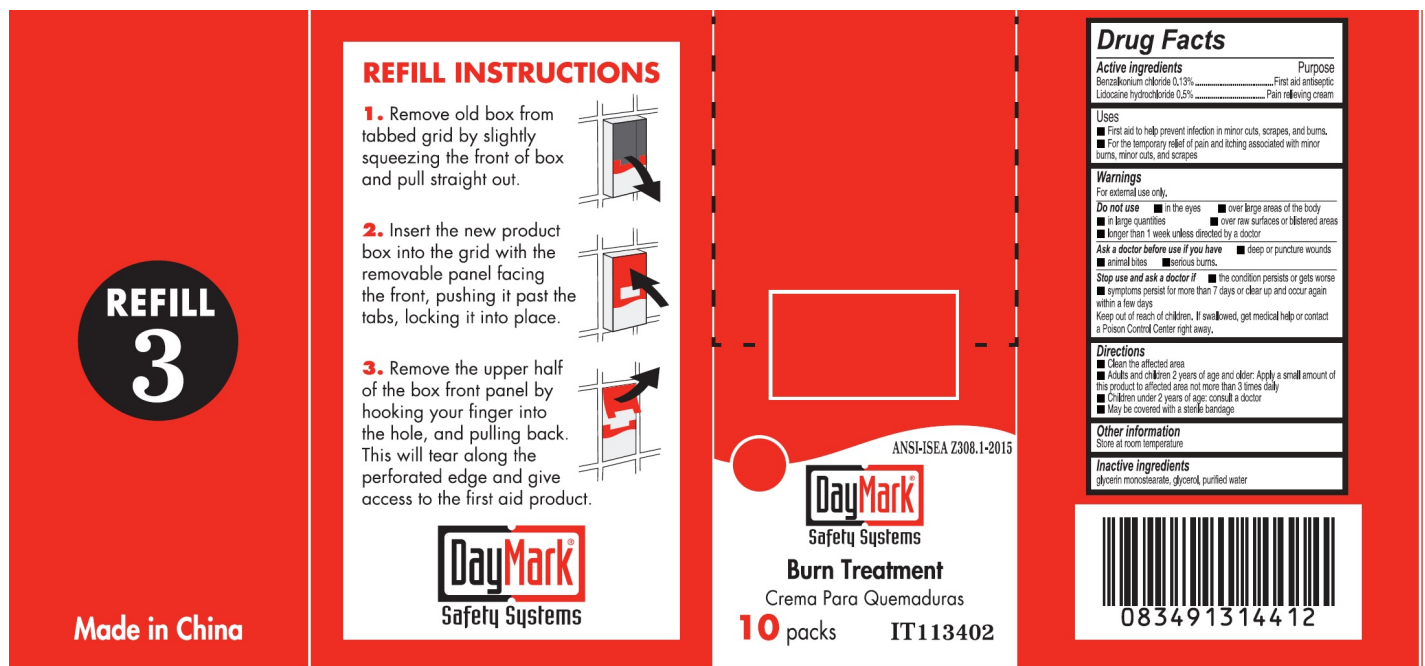
Other information

Store at room temperature

Inactive ingredients

glycerin monostearate, glycerol, purified water

Package Labeling:



REFILL 3

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49687-0017
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:49687-0017-0	10 in 1 BOX	08/10/2016	
1		0.9 g in 1 PACKAGE; 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	08/10/2016	

Labeler - CMC Group Inc. (117201448)

Revised: 12/2023

CMC Group Inc.