DYNAREX BURN CREAM- lidocaine cream Dynarex Corporation

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.

Dynarex Burn Cream

Active Ingredients

Active Ingredient Purpose

Lidocaine HCL 0.5% Topical Analgesic
Benzalkonium Chloride 0.13% Topical Antiseptic

Purpose

Temporary relief of pain and itching.

Uses

For temporary relief of pain and itching associated with:

- Sunburn
- Minor burns.
- Insect bites,
- Minor skin irritation,
- Cuts and
- Scrapes

Warnings

IFOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN [KEEP OUT OF REACH OF CHILDREN]

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

Stop Use

Stop Use and ask a doctor:

- IIIIf condition worsens or,
- if symptoms persist for more than 7 days or clear up and occur again in a few days.
- If pregnant or breast feeding, ask a health professional before use.

Do Not Use

Do Not Use:

- In the eyes
- Over large areas of the body or on deep puncture wounds, animal bites or serious burns.
- In large quantities, particularly over raw surfaces or blistered areas.

Directions

Adults and children 2 years and over:

- clean the affected area
- apply a small amount of this product on the area 3 or 4 times daily.
- may be covered with a sterile bandage

©Children under 2 years

• consult a doctor

Inactive ingredients

Buttylated hydroxy toluene, Cetomacrogol, Cetostearyl alcohol, Dimethicone, Glycerine, Glyceryl monostearate, Isopropyl myristate, Methylcellulose, Purified water, Sodium EDTA, Sodium methylparaben, Sodium propylparaben

Other Information

Other Information

- store in a cool, dry area
- 590 to 790 F (150 to 250 C)
- Tamper evident sealed packets do not use any open or torn packets

Principal Display Panel

Dynarex Burn Cream

DFAC.jpg

Reorder No. 1165

Drug Facts Active Ingredients (in each gram)...... Purpose Lidocaine HCI 0.5% Benzalkonium chloride 0.13%.....

Uses For the temporary relief of pain and itching associated with: ■ sunburn ■ minor burns ■ insect bites ■ minor skin initation ■ cuts ■ scrapes

Warnings

For external use only. Do not use **m** in the eyes **m** over large areas of the body or on deep puncture wounds, animal bites, or serious burns **m** in large quantities, particularly over raw surfaces or blistered areas. Stop use and ask a doctor if **m** the condition gets worse **m** condition deasy up and recurs within a few day **m** condition persists for more than 7 days **m** if pregnant or breast feeding, ask a health care professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison .. Topical analgesis Topical antiseption

Directions
Adults and children 2 years and over; III clean the affected area III apply a small amount of this product on the area 3 to 4 times daily III may be covered with a sterile bandage. Children under 2 years; III consult a doctor

Other Information ■ store in a cool, dry area 15°-25° C (59°-79° F)
■ tamper evident sealed packets ■ do not use any opened or torn packets

Inactive Ingredients butylated hydroxytoluene, cetomacrogol, cetostearyl alcohol, dimethicone, glycerine, glyceryl monostearate, isopropyl myristate, methycellulose, purified water, sodium £DTA, sodium methylparaben, sodium propylparaben

Reorder No. 1165





Manufactured for: **Dynarex Corporation** Orangeburg, NY 10962 www.dynarex.com Made in India

NDC# 67777-412-01

Reorder No. 1165

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First Aid Cream



Net Wt. 0.9 gram





First Aid Cream

DYNAREX BURN CREAM

lidocaine cream

Product Information

Product Type HUMAN OTC DRUG NDC:67777-412 Item Code (Source)

TOPICAL Route of Administration

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g
BENZALKO NIUM CHLO RIDE (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g

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Inactiva	Ingredients
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mactive ingredients		
Ingredient Name	Strength	
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)		
METHYLCELLULOSE (25 MPA.S) (UNII: BI55GG2WLI)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		

GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CETETH-20 (UNII: 1835H2IHHX)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
METHYLPARABEN SO DIUM (UNII: CR6 K9 C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
EDETATE SO DIUM (UNII: MP1J8 420 LU)	
WATER (UNII: 059QF0KO0R)	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67777-412-01	0.9 g in 1 PACKET; Type 0: Not a Combination Product	09/16/2015	
Marketing Information				
	Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

Labeler - Dynarex Corporation (008124539)

Packaging

Registrant - Dynarex Corporation (008124539)

Establishment					
Name	Address	ID/FEI	Business Operations		
Galentic Pharma (India) Pvt. Ltd.		650970176	manufacture(67777-412)		

Revised: 4/2016 Dynarex Corporation