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

FOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

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

Stop Use

Stop Use and ask a doctor:

- If 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
- 59o to 79o F (15o to 25o C)
- Tamper evident sealed packets do not use any open or torn packets

Principal Display Panel

Dynarex Burn Cream

DFAC.jpg

DYNAREX BURN CREAM

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67777-412
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLCELLULOSE (25 MPA.S) (UNII: BI55GG2WLI)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETETH-20 (UNII: I835H2IHHX)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYLPARABEN SODIUM (UNII: CR6K9C2NHK)	
PROPYLPARABEN SODIUM (UNII: 625NNB0G9N)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE SODIUM (UNII: MP1J8420LU)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/01/2015	

Labeler - Dynarex Corporation (008124539)

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