

LIDOCAINE- lidocaine cream
Marlex Pharmaceuticals Inc

Lidocaine 4 Percent Topical Cream

LIDOCAINE 4%- lidocaine cream

MarlexPharmaceuticals, 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.

Lidocaine 4% Topical

Drug Facts

Active ingredient

Lidocaine 4%

Purpose

Pain & Itch Relief

Use

for the temporary relief of pain associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and minor skin irritations

Warnings

For external use only. Avoid contact with eyes. Not for prolonged use.

Donotuse in large quantities, particularly over raw surfaces or blistered areas.

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days
- rash or irritation develops, persists, or increases

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

Adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily

Children under 2 years of age: Consult a doctor

Other information

- May be applied under occlusive dressing
- store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)

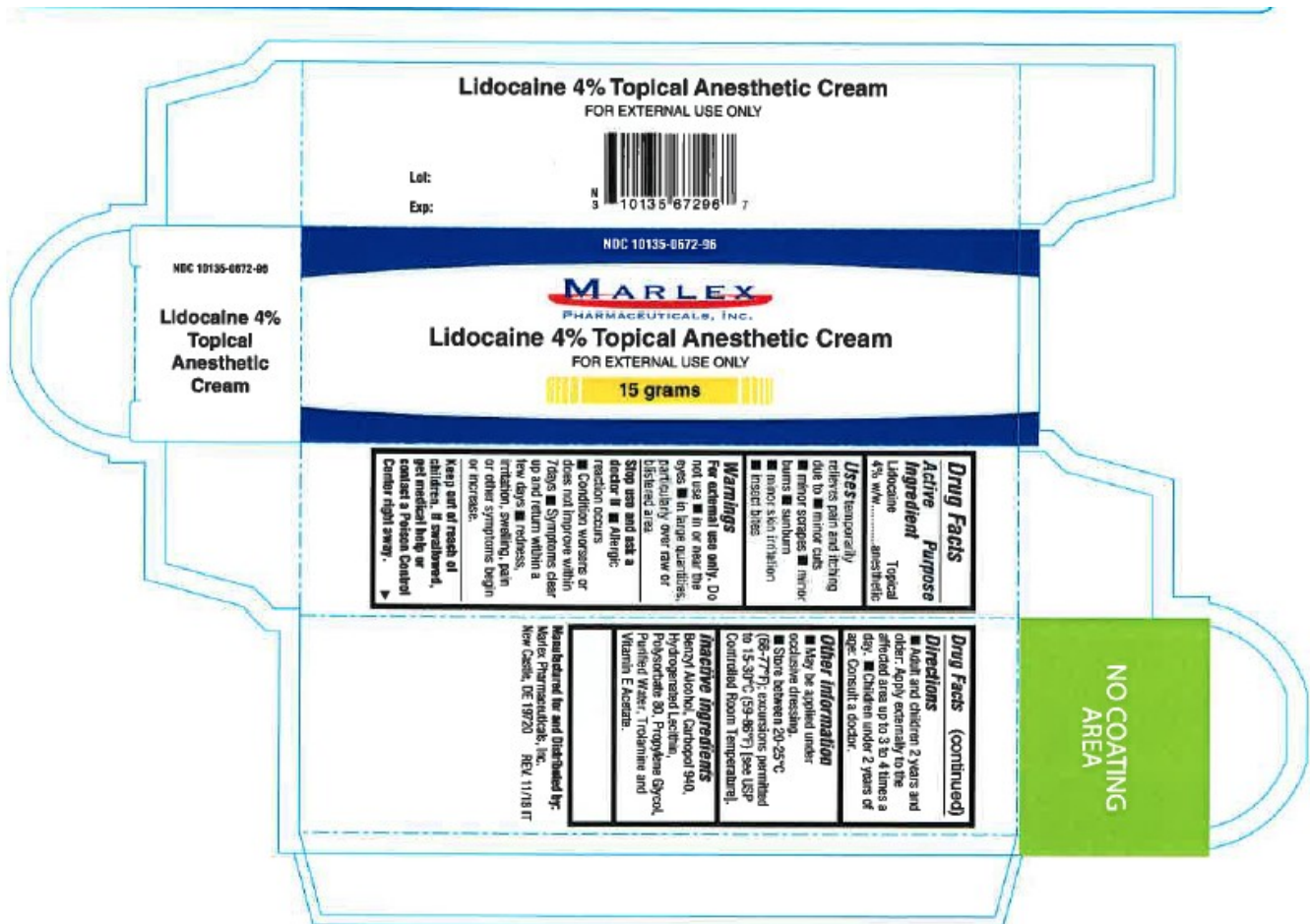
Inactive ingredients

Benzyl alcohol, carbopol 940, hydrogenated lecithin, polysorbate 80, propylene glycol, purified water, trolamine and vitamin E acetate

PRINCIPAL DISPLAY PANEL- 15gTubeCarton

Lidocaine 4% Topical Anesthetic Cream

Pain & Itch Relief Cream NET WT. 0.5 oz.(15g)



PRINCIPAL DISPLAY PANEL-30gTube Carton

Lidocaine 4% Topical Anesthetic Cream

Pain & Itch Relief Cream NET WT. (30g)



LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10135-672
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	

CHOLESTEROL (UNII: 97C5T2UQ7J)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	

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Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-672-96	1 in 1 CARTON	12/01/2018	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:10135-672-99	1 in 1 CARTON	12/01/2018	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		

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Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	12/01/2018	

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Labeler - Marlex Pharmaceuticals Inc (782540215)

Revised: 11/2023

Marlex Pharmaceuticals Inc