MERICAINE- lidocaine gel
Merit Pharmaceutical

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Mericaine ™ - LIDOCAINE 4% Topical Gel - lidocaine gel

Merit Pharmaceuticals

Drug Facts
Lidocaine 4% Gel

Active Ingredient

Lidocaine 4% w/w

Purpose

Topical Anesthetic

Uses

Temporarily relieves pain and itching due to:

- minor cuts
- minor scrapes
- sunburn
- minor skin irritations
- minor burns
- insect bites

Warnings

For external use only. Not for ophthalmic use.

Do not use:

- in or near the eyes
- in large quantities, particularly over raw surfaces or blistered areas

Stop use and ask a doctor if

- allergic reaction occurs
- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- redness, irritation, swelling, pain or other symptoms begin or increase

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 and older: Apply externally to the affected area up to 3 to 4 times a day.
- Children under 2 years of age: Consult a doctor.

Inactive Ingredients

alcohol, benzyl alcohol, carbomer, citric acid, ethoxydiglycol, propylene glycol, and purified water.

Other Information

- May be applied under occlusive dressing.
- Store at 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °F) [See USP Controlled Room Temperature].

MERICAINE
lidocaine gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30727-810
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	0.04 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30727-810-30	1 in 1 BOX	07/01/2016	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2015	

Labeler - Merit Pharmaceutical (093370369)

Registrant - Merit Pharmaceutical (093370369)

Establishment

Name	Address	ID/FEI	Business Operations
Biozone Laboratories, Inc.		962455320	manufacture(30727-810) , analysis(30727-810) , pack(30727-810) , label(30727-810)

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