

LMX4- lidocaine cream
Ferndale Laboratories, 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.

L.M.X.4

Active ingredient

Lidocaine 4% w/w

Purpose

Topical anesthetic

Uses

temporarily relieves pain and itching due to

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

Warnings

For external use only.

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: 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) [see USP Controlled Room Temperature].

Inactive ingredients

benzyl alcohol, carbomer 940, cholesterol, hydrogenated lecithin, polysorbate 80, propylene glycol, trolamine, vitamin E acetate, water

Package Labels-Principal Display Panels

Manufactured by Ferndale Laboratories, Inc.

Ferndale, MI 48220 U.S.A.

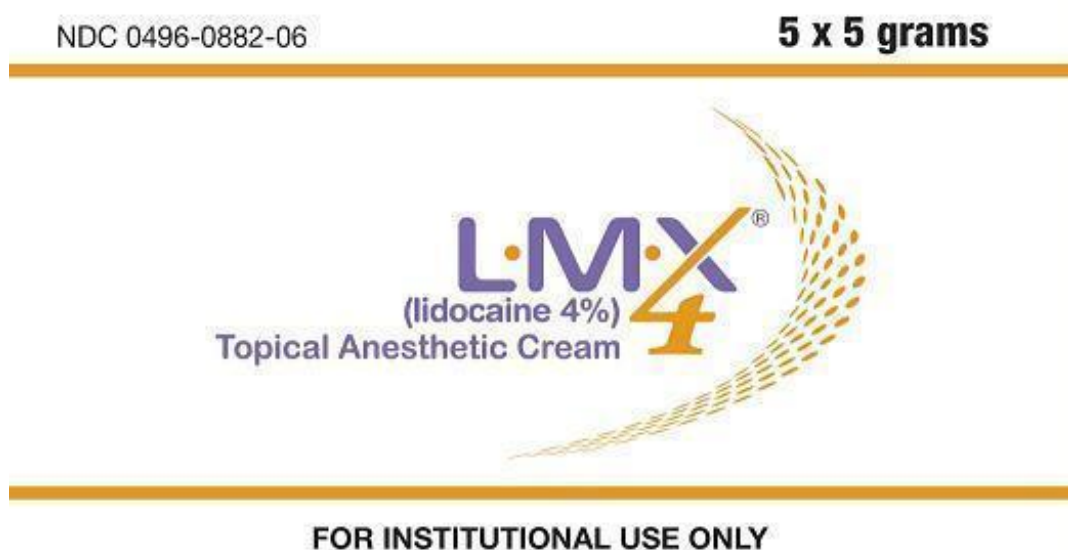
Toll free (888) 548-0900

www.ferndalelabs.com

L.M.X.4® is a registered trademark of Ferndale IP, Inc.

Tegaderm™ is a trademark of 3M Corporation.

NDC 0496-0882-06 L.M.X.4® 5 x 5 grams



NDC 0496-0882-07 L.M.X.4® 5 x 5 grams with 10 3M Tegaderm™ Transparent Dressings

NDC 0496-0882-07

5 x 5 grams

*Includes 10
3M Tegaderm™
Transparent
Dressings*

L.M.X.[®]
(lidocaine 4%)
4
Topical Anesthetic Cream



**FOR INSTITUTIONAL
USE ONLY**

FIVE 5 gram tubes + TEN 3M Tegaderm™ Transparent Dressings

NDC 0496-0882-15 L.M.X.4® 15 grams

NDC 0496-0882-15

Quick. To Care.

L.M.X.[®]₄

*Topical Anesthetic
Cream*

**Dermatologist
Recommended**

Net Wt. 15 g

NDC 0496-0882-30 L.M.X.4[®] 30 grams

Drug Facts	
Active Ingredient	Purpose
Lidocaine 4% w/w	Topical anesthetic
Uses Temporarily relieves pain and itching due to	
■ minor scrapes	■ minor cuts
■ minor burns	■ sunburn
■ insect bites	■ insect bites
■ minor skin irritations	
Warnings	
For external use only.	
■ 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	
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].	
Inactive ingredients	
benzyl alcohol, carboner 940, cholesteryl, hydrogenated lecithin, polysorbate 80, propylene glycol, purified water, triethanolamine, and vitamin E acetate	



Dermatologist
Recommended

L.M.X.4®
(lidocaine 4%)
Topical Anesthetic Cream

NET WT.
30 grams

Dermatologist
Recommended

NDC 0496-0882-30

L.M.X.4®
(lidocaine 4%)
Topical Anesthetic Cream

NET WT.
30 grams

L.M.X.4®
(lidocaine 4%)
Topical
Anesthetic
Cream

Dermatologist
Recommended



Ferndale, MI 48220 U.S.A.
Toll free (888) 548-0900

L.M.X.4® is a registered
trademark of Ferndale IP Inc.

See end flap for Lot No. and exp. date.
Rev.: 02/16

NDC 0496-0882-71 L.M.X.4® 30 grams with 10 3M Tegaderm™ Transparent Dressings

NDC 0496-0882-71

Net Wt. 30 grams

Includes 10
3M Tegaderm™
Transparent
Dressings

L.M.X.4®
(lidocaine 4%)
Topical Anesthetic Cream

ONE 30 gram tube + TEN 3M Tegaderm™ Transparent Dressings

NDC 0496-0882-05 L.M.X.4 5 grams

NDC 0496-0882-05

NET WT.
5 grams

PACKAGE
NOT CHILD-
RESISTANT

LMX⁴
(lidocaine 4%)
Topical Anesthetic Cream

THIS PACKAGE
FOR HOUSEHOLDS
WITHOUT YOUNG
CHILDREN.

LMX4

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0496-0882
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 (UNII: 4Q93RCW27E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0882-06	5 in 1 CARTON	01/03/2011	
1	NDC:0496-0882-05	5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0496-0882-07	5 in 1 BOX	01/03/2011	
2	NDC:0496-0882-05	5 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0496-0882-15	15 g in 1 TUBE; Type 0: Not a Combination Product	01/03/2011	
4	NDC:0496-0882-30	30 g in 1 TUBE; Type 0: Not a Combination Product	01/03/2011	
5	NDC:0496-0882-05	5 g in 1 TUBE; Type 0: Not a Combination Product	01/03/2011	
6	NDC:0496-0882-71	1 in 1 BOX	01/03/2011	
6	NDC:0496-0882-30	30 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
OTC monograph not final	part348	01/03/2011	

Labeler - Ferndale Laboratories, Inc. (005320536)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0882)

Revised: 5/2020

Ferndale Laboratories, Inc.