LMX5- 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.

LMX5 (lidocaine 5%) Anorectal Cream

Active ingredient

Lidocaine 5% w/w

Purpose

Local anesthetic

Uses

temporarily relieves pain and itching due to anorectal disorders

Warnings

When using this product

- avoid contact with eyes
- do not exceed recommended dosage unless directed by a doctor

Stop use and ask a doctor if

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

Keep out of reach of children.

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

Directions

- When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.
- Adults and Children 12 years and older: Apply to the affected area up to 6 times a day.
- Children under 12 years of age: Consult a doctor.

Other information

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, chloesterol, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, trolamine, and vitamin E acetate

Package Label

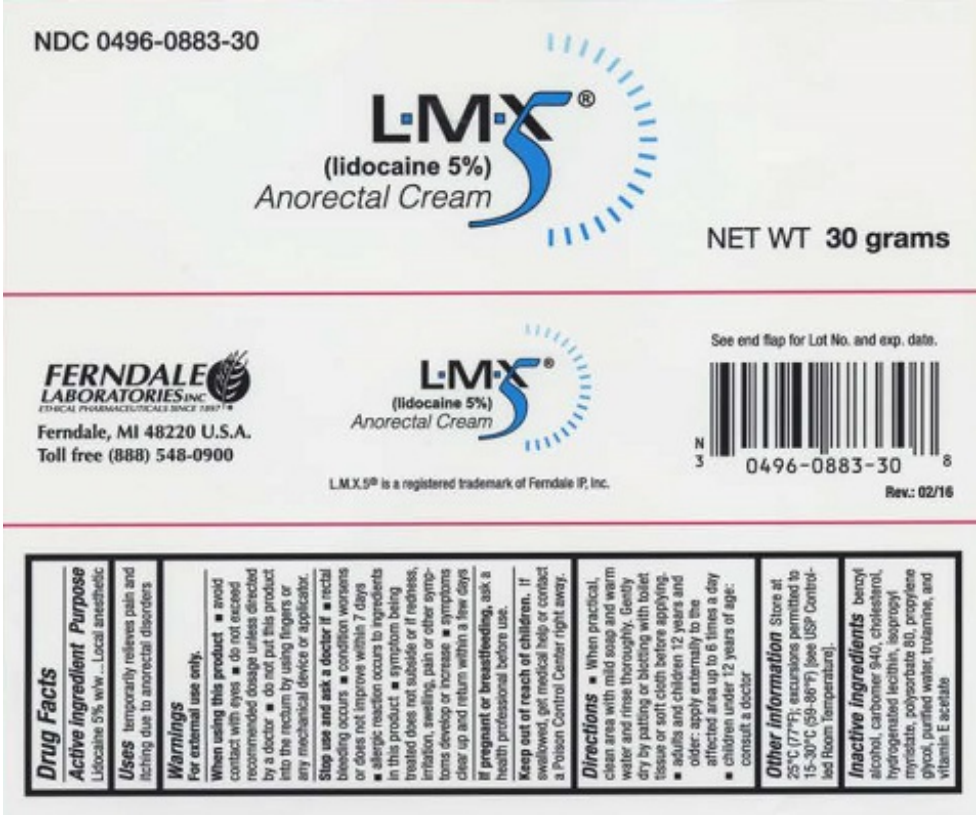
Manufactured for Ferndale Healthcare Inc.

Ferndale, MI 48220 U.S.A.

Toll free (888) 548-0900

www.ferndalehealthcare.com

L.M.X.5® is a registered trademark of Ferndale, IP Inc.
30 gram NDC 0496-0883-30



LMX5

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0496-0883
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0883-30	30 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2003	
2	NDC:0496-0883-15	15 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2003	
3	NDC:0496-0883-97	1 g in 1 POUCH; Type 0: Not a Combination Product	10/01/2003	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	10/01/2003	

Labeler - Ferndale Laboratories, Inc. (005320536)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0883)

Revised: 10/2018 Ferndale Laboratories, Inc.