

LMX5- lidocaine cream
Ferndale Laboratories, Inc.

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 homopolymer, 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

NDC 0496-0883-30



NET WT. 30 grams

FERNDALE LABORATORIES, INC. ETHICAL PHARMACEUTICALS SINCE 1897
Ferndale, MI 48220 U.S.A.
Toll free (888) 548-0900



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See end flap for Lot No. and exp. date.

Rev.: 10/24

Drug Facts

Active ingredient Purpose

Lidocaine 5% w/w ... Local anesthetic

Uses temporarily relieves pain and itching due to anorectal disorders

Warnings

For external use only.

When using this product ■ avoid contact with eyes ■ do not exceed recommended dosage unless directed by a doctor ■ do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if ■ rectal bleeding occurs ■ condition worsens or does not improve within 7 days ■ allergic reaction occurs to ingredients in this product ■ symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase ■ symptoms clear up and return within a few days

If pregnant or breastfeeding, 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 ■ 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 externally 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 homopolymer, cholesterol, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, trolamine, and vitamin E acetate

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 Drug	M015	10/01/2003	

Labeler - Ferndale Laboratories, Inc. (005320536)**Establishment**

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