

RECTASMOOTH- lidocaine 5% cream

Leading Pharma, LLC

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 5%

Active Ingredient

Lidocaine 5% w/w

Purpose

Local anesthetic

Uses

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

WARNINGS:

For external use only.

When using this product

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

Stop use and ask 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

Keep out of the 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 six times a day.
- Children under 12 years of age: Consult a doctor
- To use finger cots: Roll one finger cot over finger. Gently squeeze cream onto finger cot. Smooth a layer of the cream over the affected area.

Other Information

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

Inactive Ingredients

cetyl alcohol, glyceryl monostearate SE, methylparaben, propylene glycol, propylparaben, purified water, white petrolatum, white wax

Lidocaine 5%

LEADING P H A R M A	NDC 69315-301-30	Alleviates: <ul style="list-style-type: none">• Pain• Burning• Itching• Abrasions
RectaSmoothie™ Lidocaine 5% Hemorrhoidal Cream		
<i>Maximum Over-the-Counter Strength</i>		NET WT. 30 grams
Drug Facts		Manufactured for: Leading Pharma, LLC Fairfield, NJ 07004, Toll-free (844)-740-7500 www.leadingpharma.com
Active Ingredient: Lidocaine 5% w/w Purpose: Local anesthetic		 N 3 69315 30130 2
Warnings: See outer carton.		
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 six times a day. ■ Children under 12 years of age: consult a doctor.		
		See Lot No. and exp. date on tube crimp. REV.: 06/15



RECTASMOOTHIE

lidocaine 5% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69315-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69315-301-30	1 in 1 CARTON	05/15/2016	
1		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 final	part346	04/01/2011	

Labeler - Leading Pharma, LLC (079575060)**Registrant** - Leading Pharma, LLC (079575060)**Establishment**

Name	Address	ID/FEI	Business Operations
Lyne Laboratories, Inc.		053510459	MANUFACTURE(69315-301)

Revised: 12/2017

Leading Pharma, LLC