RECTICARE- 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.

RECTICARE Lidocaine 5% Anorectal Cream

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 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.
- To use finger cots: Roll one finger cot over finger. Gently squeeze cream onto finger cot. Smooth a layer of the cream over 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

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

Package Label



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Drug Facts (continued)

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Questions? Toll free (888) 548-0900

child-resistant cap: PUSH DOWN AND TURN COUNTERCLOCKWISE

To open

See bottom panel for Lot No. and exp. date.

Recommended by

Colon & Rectal Surgeons



Hemorrhoids & Other Anorectal Disorders

Rection

ecticare

Lidocaine 5% Anorectal Cream

Strength
Available

Relieves Pain

Relieves Itching

Relieves Burning

For coupons and information visit www.recticare.com

NET WT. 30 grams





RectiCare® is a registered trademark of Ferndale IP, Inc.

RECTICARE

lidocaine cream

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0496-0892

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		
CHOLESTEROL (UNII: 97C5T2UQ7J)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
POLYSORBATE 80 (UNII: 6OZP39ZG8H)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
TROLAMINE (UNII: 903K93S3TK)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)			

l	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:0496-0892-	30 g in 1 TUBE; Type 0: Not a Combination Product	03/09/2012			
	NDC:0496-0892- 15	15 g in 1 TUBE; Type 1: Convenience Kit of Co-Package	01/19/2015			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part346	03/09/2012		

Labeler - Ferndale Laboratories, Inc. (005320536)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0892)	

Revised: 4/2021 Ferndale Laboratories, Inc.