

RECTICARE- lidocaine cream
Ferndale Laboratories, Inc.

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

Drug Facts (continued)

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 ▶

Drug Facts (continued)

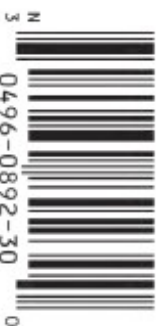
Other information Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

Inactive ingredients benzyl alcohol, carbonar 940, cholesterol, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, triammine, and vitamin E acetate

Questions? Toll free (888) 548-0900

To open
child-resistant cap:
**PUSH DOWN AND TURN
COUNTERCLOCKWISE**

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



Rev.: 03/21

Rapid Pain Relief for
Hemorrhoids & Other
Anorectal Disorders

RectiCare[®]
Lidocaine 5% Anorectal Cream

Highest
Non-Rx Lidocaine
Strength
Available

Recommended by
Colon & Rectal Surgeons

- ✓ Relieves Pain
- ✓ Relieves Itching
- ✓ Relieves Burning

For coupons and information visit www.recticare.com

NET WT. 30 grams

Rapid
Pain Relief for
Hemorrhoids & Other
Anorectal Disorders

**Highest
Non-Rx Lidocaine
Strength
Available**

RectiCare®
Lidocaine 5%
Anorectal Cream

- ✓ Relieves Pain
- ✓ Relieves Itching
- ✓ Relieves Burning

Recommended by
Colon & Rectal Surgeons

NET WT. 30 grams

Drug Facts (continued)	
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 ▶	
Drug Facts (continued)	
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	
Drug Facts	Active Ingredient Lidocaine 5% w/w ... Local anesthetic Purpose Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders.

Manufactured for
FERNDALE
HEALTHCARE, INC.
by Ferndale Laboratories, Inc.
Ferndale, MI 48220 U.S.A.
Toll free (888) 548-0900
www.ferndalehealthcare.com
RectiCare® is a registered trademark of Ferndale LP, Inc.

RECTICARE

lidocaine cream

Product Information

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: 9O3K93S3TK)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0892-30	30 g in 1 TUBE; Type 0: Not a Combination Product	03/09/2012	
2	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 Drug		M015	03/09/2012	

Labeler - Ferndale Laboratories, Inc. (005320536)

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