

RECTICARE- lidocaine and glycerin cloth
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 Medicated Anorectal Wipes

Active Ingredients

Lidocaine 5% w/w

Glycerin 20% w/w

Purpose

Lidocaine 5% w/w.....Local anesthetic

Glycerin 20% w/w.....Protectant

Uses

- helps relieve the pain, itching and burning associated with anorectal disorders
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects irritated and inflamed perianal skin

Warnings

For external use only

Do not

- exceed the recommended daily dosage unless directed by a doctor
- put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- an allergic reaction develops
- condition worsens or does not improve within 7 days
- redness, irritation, swelling, pain or other symptoms begin or increase
- bleeding occurs

Keep out of reach of children. If swallowed, seek medical attention or contact a Poison Control Center right away.

Directions

- when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently apply wipe to the affected area by patting and then discard
- adults and children 12 years & older: apply up to 6 times daily - or after each bowel movement
- children under 12 years: consult a doctor

Inactive Ingredients

benzyl alcohol, citric acid, purified water

Package Label

To Open: Fold back on dotted line. Tear on arrow or use scissors.

Rapid Pain Relief for Hemorrhoids
& other Anorectal Disorders

NDC 0496-0980-76

Highest
Lidocaine Strength
Wipe Available

RectiCare[®]
Medicated Anorectal
with Lidocaine and Glycerin *wipes*

- ✓ Relieves Pain
- ✓ Relieves Itching
- ✓ Protects & Soothes

Manufactured for
Ferdale Healthcare[®], Inc.
by Ferdale Laboratories, Inc.
Ferdale, MI 48220 U.S.A.
Toll free (866) 546-0900
www.ferdalehealthcare.com

Contains 1
Single-Use Wipe

Rev: 05/15

Drug Facts	
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RECTICARE

lidocaine and glycerin cloth

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0496-0980
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
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	200 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0980-65	12 in 1 CARTON	01/01/2016	
1	NDC:0496-0980-76	6 g in 1 POUCH; 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	01/01/2016	

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

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0980)

Revised: 11/2019

Ferndale Laboratories, Inc.