

RECTICARE ADVANCED- lidocaine and mineral oil and phenylephrine hcl and white petrolatum 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 Advanced Hemorrhoidal Cream

Active ingredients

Lidocaine 5% w/w
Mineral Oil 17% w/w
Phenylephrine HCl 0.25% w/w
White Petrolatum 39% w/w

Purpose

Lidocaine 5% w/w.....Local anesthetic
Mineral Oil 17% w/w.....Protectant
Phenylephrine HCl 0.25% w/w.....Vasoconstrictor
White Petrolatum 39% w/w.....Protectant

Uses

- helps relieve the pain, itching and burning associated with hemorrhoids
- temporarily reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders
- temporarily provides a coating for relief of anorectal discomforts
- temporarily protects irritated areas and inflamed perianal skin

Warnings

For external use only.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug for high blood pressure or depression

When using this product

- avoid contact with eyes
- do not exceed recommended daily 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

- 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

If pregnant or breastfeeding,

ask a doctor before use.

Keep out of reach of children.

If swallowed, get medical help 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 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 4 times daily
- 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

ceteth 20, cetostearyl alcohol, citric acid, propylparaben, purified water

Package Label

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression

When using this product ■ avoid contact with eyes ■ do not exceed recommended daily 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 ■ 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

Drug Facts (continued)

If pregnant or breastfeeding, ask a doctor before use. Keep out of reach of children. If swallowed, get medical help 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 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 4 times daily ■ children under 12 years of age: consult a doctor

Drug Facts (continued)

Other Information
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Inactive ingredients
cetylal, 20, cetylalcohol, citric acid, propylparaben, purified water

Questions? Toll free (888) 548-0900

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



ADVANCED
FORMULA

RectiCare[®]
ADVANCED
HEMORRHOIDAL CREAM

Highest Lidocaine &
Phenylephrine HCl Strengths
Available Without a
Prescription

Designed Specifically
for Hemorrhoids

- ✓ Shrinks Swollen Hemorrhoidal Tissue
- ✓ Relieves Pain
- ✓ Relieves Itching
- ✓ Relieves Burning

For coupons and information visit
www.recticare.com

RectiCare[®] is Recommended by Colon & Rectal Surgeons

NET WT. 30 grams

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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.
See bottom panel for Lot No. and exp. date.
Rev.: 09/19

Drug Facts

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Mineral Oil 17% w/w Protectant
Phenylephrine HCl
0.25% w/w Vasconstrictor
White Petrolatum
39% w/w Protectant

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RECTICARE ADVANCED

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0496-0978
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
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	170 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 g

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)

PETROLATUM

390 mg
in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETETH-20 (UNII: I835H2IHHX)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0496-0978-15	15 g in 1 TUBE; Type 0: Not a Combination Product	04/01/2016	
2	NDC:0496-0978-30	30 g in 1 TUBE; Type 0: Not a Combination Product	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	04/01/2016	

Labeler - Ferndale Laboratories, Inc. (005320536)

Establishment

Name	Address	ID/FEI	Business Operations
Ferndale Laboratories, Inc.		005320536	manufacture(0496-0978)

Revised: 4/2021

Ferndale Laboratories, Inc.