

ANORECTAL LIDOCAINE CREAM- lidocaine cream

RUGBY LABORATORIES

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.

ANORECTAL Lidocaine 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 breast feeding, 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.

Other information

Store at room temperature (20-25°C) (68-77°F). Avoid excessive heat and cold. Protect from sunlight.

Inactive ingredients

benzyl alcohol, carbomer, hydrogenated lecithin, isopropyl myristate, polysorbate 80, propylene glycol, purified water, triethanolamine, vitamin E

Questions?

1-800-645-2158

Compare to the active ingredient in Recticare® Anorectal Cream††

- **For the temporary relief of anorectal itching & discomfort associated with hemorrhoids**
- **Helps relieve pain, soreness & burning**
- **Highest OTC lidocaine strength available**

+ 10 FINGER COTS*

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF THE TUBE IS DAMAGED OR TAMPERED WITH.

Close cap tightly after each use.

††This product is not manufactured or distributed by Ferndale Healthcare®, Inc., a subsidiary of Ferndale Pharma Group, Inc., owner of the registered trademark RectiCare®.

Packaging

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1339
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Route of Administration	TOPICAL
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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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1339-28	1 in 1 CARTON	09/04/2021	
1		28 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	09/04/2021	

Labeler - RUGBY LABORATORIES (079246066)**Registrant** - Strive Pharmaceuticals Inc. (080028013)

Revised: 9/2021

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