

RECTOPROTECT- lidocaine cream
Akron Pharma Inc.

RectoProtect (Lidocaine 5% Anorectal Cream)

Pain Relief for Hemorrhoids & Other Anorectal Disorders

Active ingredient

Lidocaine 5% w/w

Purpose

Local anesthetic

Uses

Temporarily relieves pain and itching due to anorectal disorders

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

Warnings

When using this product

- avoid contact with eyes
- do not exceed recommended dosage unless directed by a doctor

Stop use and ask a doctor if

- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- allergic reaction occurs
- redness, irritation, swelling, pain or other symptoms begin or increase
- symptoms clear up and return within a few days

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

Other information

- May be applied under occlusive dressing.
- Store at room temperature, 20–25°C (68–77°F) Excursions permitted 15–30°C (59–86°F) [see USP Controlled Room Temperature].

Inactive ingredients

Aloe barbadensis leaf juice, Benzyl alcohol, Carbomer, Cholesterol, Isopropyl myristate, Mineral Oil, Polysorbate 80, Propylene Glycol, Purified Water, Tocopherol, Trolamine

Questions or comments?

Call toll-free 1-877-255-6999

Manufactured for:

Akron Pharma Inc.

Fairfield, Nj 07004

www.akronpharma.com

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Lidocaine 5% Anorectal Cream
Pain Relief for Hemorrhoids & Other Anorectal Disorders

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Rev.:12/2024
NDC 71399-0050-2

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Lidocaine 5% Anorectal Cream

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RectoProtect™
Lidocaine 5% Anorectal Cream
Pain Relief for Hemorrhoids & Other Anorectal Disorders

✓ Relieves Pain
✓ Relieves Itching
✓ Relieves Burning

**Highest Non-Rx
Lidocaine Strength Available**

Net wt. 30 g

Drug Facts

| Active Ingredient | Purpose |
|-------------------|------------------|
| Lidocaine 5% w/w | Local anesthetic |

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RectoProtect™
Lidocaine 5% Anorectal Cream

RECTOPROTECT

lidocaine cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71399-0050 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) | LIDOCAINE | 5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| ALOE BARBADENSIS LEAF JUICE (UNII: ZY81Z83H0X) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| CARBOMER (UNII: 0A5MM307FC) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |

Product Characteristics

| | | | |
|-----------------|-------------------|---------------------|--|
| Color | white (clear gel) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:71399-0050-2 | 1 in 1 CARTON | 01/06/2025 | |
| 1 | | 30 g in 1 PACKAGE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | M017 | 01/06/2025 | |

