LIDOCAINE 5% TOPICAL ANORECTAL CREAM- lidocaine 5% topical anorectal cream cream

Mohnark Pharmaceuticals Inc.

Active Ingredients

Lidocaine 5% w/w

Purpose

Local Anesthetic

Uses

helps relieves 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 doctor if

- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- allergic reaction occurs
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase
- symptoms clear up and return in a few days

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 6

- times a day.
- Children under 12 years of age: consult a doctor.

Other information

• Store at USP controlled room temperature 20-25 °C (68-77 °F).

Inactive ingredients

benzyl alcohol, carbomer 940, cholesterol, hydrogenated lecithin, polysorbate 80, propylene glycol, tocopheryl acetate, trolamine, water.

Dosage

50 milligrams/gram per application

Usage

- Adults and children 2 years and older: apply externally to the affected area up to 3-4 times a day.
- Children under 2 years of age: consult a doctor

Package Label



Drug Facts

Active Ingredients Purpose Lidocaine 5% w/w...Local anesthetic

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Lidocaine 5%

MOHNARK

Pharmaceuticals, Inc.

Manufactured by:

Mohnark Pharmaceuticals, Inc.

Davie, Florida 33314 USA

Questions or comments?

Toll free: 1-866-611-5206

Cream

Topical Anorectal

Pain Relief for Hemorrhoids & other Anorectal Disorders

Topical Anorectal Cream

✓Relieves Itching ✓ Relieves Burning

Lidocaine 5%

Topical Anorectal Cream



C52315

LIDOCAINE 5% TOPICAL ANORECTAL CREAM

lidocaine 5% topical anorectal cream cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73715-002

Route of Administration RECTAL, TOPICAL

Active Ingredient/Active Moiety

| | Ingredient Name | Basis of Strength | Strength |
|-----|-----------------|--------------------------|----------|
| - 1 | | | |

LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987) LIDOCAINE 5.25 g in 100 g

Inactive Ingredients

| Ingredient Name | Strength | | |
|-----------------------------------|---------------|--|--|
| POLYSORBATE 80 (UNII: 60ZP39ZG8H) | 2 g in 100 g | | |
| WATER (UNII: 059QF0KO0R) | 80 g in 100 g | | |

Packaging

| P | Packaging | | | | |
|---|---|--|-------------------------|-----------------------|--|
| # | # Item Code Package Description | | Marketing Start Date | Marketing End Date | |
| 1 | NDC:73715-002- 01 30 g in 1 TUBE; Type 0: Not a Combination Product | | 06/15/2020 | | |

Marketing Information

| ria keting information | | | | |
|------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC Monograph Drug | M015 | 06/15/2020 | | |

Labeler - Mohnark Pharmaceuticals Inc. (117013830)

| Establishment | | | | | |
|------------------------------|---------|-----------|------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Mohnark Pharmaceuticals Inc. | | 117013830 | manufacture(73715-002) | | |

Revised: 1/2024 Mohnark Pharmaceuticals Inc.