

RECTAEASE HEMORRHOID RELIEF CREAM- lidocaine cream
Trifecta Pharmaceuticals USA LLC

RectaEase Hemorrhoid Relief Cream

Drug Facts

Active Ingredient

Lidocaine 5% w/w

Purpose

Local Anesthetic

Uses

Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders.

Warning Section

For External Use Only

Stop use and ask a doctor

Rectal bleeding occurs

Condition worsens

Symptoms persist for more than 7 days or clear up and return within a few days

Symptoms being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

When using this product

Avoid contact with the eyes

do not use more than directed unless told to do so by a doctor

do not put directly into the rectum by using fingers or any mechanical device or applicator

If Pregnant or Breast Feeding

Ask doctor before use

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away

Directions

Directions:

When practical, clean the affected area with mild soaping warm water and rinse thoroughly.

Gently dry by patting or blotting with a toilet tissue or soft cloth before applying.

Adult and children 12 years of age and older, apply to affected area not more than 6 times a day.

Children under 12 years of age: do not use, ask a doctor

Other Information

Store at 20°-25°C (68°-77°F)

Inactive Ingredients

Benzyl alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl myristate, Propylene glycol, Trolamine, Vitamin E, polysorbate 80, propylene glycol, purified water

Questions or Comments

Call 1-888-296-9067

Distributed By

Trifecta Pharmaceuticals USA™

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Packaging

OUTSIDE BOX



INNER TUBE



RECTAEASE HEMORRHOID RELIEF CREAM

lidocaine cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:69396-070 |
| 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 |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69396-070-01 | 1 in 1 BOX | 04/19/2021 | |
| 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 Drug | M015 | 04/19/2021 | |

Revised: 2/2024

Trifecta Pharmaceuticals USA LLC