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.
$\qquad$

## Drug Facts

## Active ingredient

## Purpose

Lidocaine 5\%. Local anesthetic

Uses For temporary relief of pain, soreness and burning.

## Warnings

For external use only
When using this product do not get into eyes.
Stop use and ask a doctor if • condition worsens or does not improve within 7 days $\cdot$ do not exceed the
recommended daily dosage unless directed by a doctor

- in case of bleeding, consult a doctor promptly • do not put this product into the rectum by using fingers or any mechanical device or applicator

Certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or
increase, discontinue use and consult a doctor
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions•Apply externally to affected area up to 6 times daily. • Gently dry by patting or blotting with tissue or a soft
cloth before application of this product. • 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 $25^{\circ} \mathrm{C}\left(77^{\circ} \mathrm{F}\right)$;
excursions permitted to $15-30^{\circ} \mathrm{C}\left(59-86^{\circ} \mathrm{F}\right)$.

## Inactive ingredients

Benzyl Alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine, Vitamin E Acetate.


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This product is not manufactured or distributed by Ferndale Healithcare a subsidiary of Ferndale Pharma Group, Inc., the distributor of RectiCare Anorectal Cream.

## ANORECTAL

lidocaine cream

## Product Information

## Product Type

HUMAN OTC DRUG
Item Code (Source)
NDC:11822-1234
Route of Administration
TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Lidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)

## Basis of Strength

Lidocaine

## Strength

5 g in 100 mL

## Inactive Ingredients

Ingredient Name
Strength
Benzyl alcohol (UNII: LKG8494WBH)
Cholesterol (UNII: 97C5T2UQ7J)
HYDRO GENATED SO YBEAN LECITHIN (UNII: H1109Z9J4N)
Isopropyl Myristate (UNII: 0RE8K4LNJS)
Polysorbate 80 (UNII: 6OZP39ZG8H)
Propylene Glycol (UNII: 6DC9Q167V3)
Water (UNII: 059QF0KO0R)
Trolamine (UNII: 9O3K93S3TK)
.ALPHA.-TO COPHEROL ACETATE (UNII: 9E8 X80D2L0)

| Packaging |  |  |  |
| :---: | :---: | :---: | :---: |
| \# Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:11822-1234-1 | 1 in 1 CARTON | 03/24/20 16 |  |
| 1 | 28.3 mL in 1 TUBE; Type 0: Not a Combination Product |  |  |
| Marketing Information |  |  |  |
| Marketing Category | y Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part346 | 03/24/20 16 |  |

## Labeler - Rite Aid (014578892)

Registrant - Product Quest (927768135)

## Establishment

| Name | Address | ID/FEI | Business Operations |
| ---: | :---: | :---: | :---: |
| Product Quest | 927768135 | manufacture $(11822-1234)$, label $(11822-1234)$ |  |

