

ANORECTAL EQUATE- lidocaine cream

Walmart

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.

Drug Facts FR#44-61PQ

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 • 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

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.

Other information Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F).

Inactive ingredients

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

Compare
to Recticare®
Active
Ingredient*

Hemorrhoidal Relief Cream

with Lidocaine 5%

- Helps relieve pain, soreness and burning
- Pain relief from hemorrhoids and other anorectal disorders
- Highest lidocaine strength available over the counter
- Contains soothing Vitamin E
- Includes 10 finger cots

NET WT 1 OZ (30g)



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- 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.

Other information Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F).

Inactive ingredients

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Satisfaction guaranteed – Or we'll replace it or give you your money back. For questions or comments or to report an undesired reaction or side effect, please call **1-888-287-1915**.

DISTRIBUTED BY:
Wal-Mart Stores, Inc.,
Bentonville, AR 72716

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

ANORECTAL EQUATE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-655
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 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	

HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-655-01	1 in 1 CARTON	04/16/2016	
1		29.6 mL 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	04/16/2016	

Labeler - Walmart (051957769)

Registrant - Product Quest (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest		927768135	manufacture(49035-655) , label(49035-655)