ANORECTAL- lidocaine cream Rite Aid

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

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

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° 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.



Includes 10 finger cots

Caution: the finger cots contain natural

rubber latex which may cause allergic reactions



*Compare to the active ingredients of Recticare® Anorectal Cream

anorectal cream

lidocaine 5%

local anesthetic

NET WT 1 OZ (28.3 g)



anorectal cream

lidocaine 5%

local anesthetic

NET WT 1 OZ (28.3 g)



anorectal cream

lidocaine 5%

local anesthetic

NET WT 1 OZ (28.3 g)



highest lidocaine strength available OTC



DISTRIBUTED BY: RITE AID, 30 HUNTER LANE CAMP HILL, PA 17011



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

ANORECTAL.

lidocaine cream

Product	Information
1 I Uuuct	IIIIVI IIIAUVII

Product Type HUMAN OTC DRUG Item Code (Source) NDC:11822-1234

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthLidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)Lidocaine5 g in 100 mL

Inactive Ingredients

mactive ingredients		
Ingredient Name	Strength	
Benzyl alcohol (UNII: LKG8494WBH)		
Cholesterol (UNII: 97C5T2UQ7J)		
HYDRO GENATED SO YBEAN LECITHIN (UNII: H1109Z9J4N)		
Isopropyl Myristate (UNII: 0 RE8 K4LNJS)		
Polysorbate 80 (UNII: 6OZP39ZG8H)		
Propylene Glycol (UNII: 6DC9Q167V3)		
Water (UNII: 059QF0KO0R)		
Trolamine (UNII: 9O3K93S3TK)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-1234-1	1 in 1 CARTON	03/24/2016	
1		28.3 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	03/24/2016		

Labeler - Rite Aid (014578892)

Registrant - Product Quest (927768135)

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

Revised: 6/2018 Rite Aid