ANORECTAL- lidocaine cream Amerisource Bergen

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.

Anorectal Cream [GNP]

Active ingredient

Purpose

Lidocaine 5%.....Local Anesthetic

Uses

For temporary relief of local and anorectal discomfort associated with anorectal discomfort or inflammation.

Warnings For external use only.

When using this product • do not get into eyes. • do not exceed the recommended daily 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 a doctor if • condition worsens or does not improve within 7 days. • in case of bleeding, consult a doctor promptly • 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.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children.

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

Directions

Cleanse affected area and gently dry. Apply externally to the affected area up to 6 times daily, especially at night, in the morning or after each bowel movement • Children under 12 years of age: consult a doctor.

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.

Questions?

888-793-8450



Active ingredient Lidocaine 5%	Purpose Local Anesthetic
Uses For temporary relief of local and anorectal of anorectal discomfort or inflammation.	liscomfort associated with
<i>Watnings</i> For external use only.	
When using this product • do not get into eyes. • daily dosage unless directed by a doctor • do not p using fingers or any mechanical device or applicate	out this product into the rectum by
Stop use and ask a doctor if - condition worsens in case of bleeding, consult a doctor promptly - C reactions to ingredients in this product. If the symp subside or if redness, initiation, swelling, pain, or o discontinue use and consult a doctor.	Certain persons can develop allergic tom being treated does not
If pregnant or breastfeeding, ask a health profes	sional before use.
Keep out of reach of children. If swallowed, get h Center right away.	elp or contact a Poison Control
Ditections Cleanse affected area and gently dry area up to 6 times daily, especially at night, in the n movement - Children under 12 years of age: consu	noming or after each bowel
Other Information Store at 25° C (77°F); excurs	ions permitted to 15-30° C (59-86° F).
Inactive Ingredients Benzyl Alcohol, Carbom .ecithin, Isopropyl Myristate, Polysorbate 80, Prop Irolamine, Vitamin E Acetate.	ar 940, Cholesterol, Hydrogenated ylene Glycol, Purified Water,
Questions? 888-793-8450	



Distributed By AmerisourceBergen 1300 Morris Drive Chesterbrook, PA 19087 Questions or Concerns? www.mygnp.com



*This product is not manufactured or distributed by RectiCare @

lidocaine cream						
Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC	NDC:46122-652	
Route of Administration	TOPICAL					
Active Ingredient/Active	Moiety					
Ingred	lient Name		Basis of Stren	gth	Strength	
LIDOCAINE (UNII: 98PI200987) (L	DOCAINE - UNII:98PI200987)		LIDOCAINE		5 g in 100 g	
Inactive Ingredients	Ingredient Name				Strength	
BENZYL ALCOHOL (UNII: LKG849	4WBH)					
CARBOMER 940 (UNII: 4Q93RCW	27E)					
CHOLESTEROL (UNII: 97C5T2UQ	7J)					
HYDROGENATED SOYBEAN LEC	CITHIN (UNII: H1109Z9J4N)					
ISOPROPYL MYRISTATE (UNII: 0						
POLYSORBATE 80 (UNII: 60ZP3	· ·					
PROPYLENE GLYCOL (UNII: 6DC)	9Q167V3)					
WATER (UNII: 059QF0K00R)						
TROLAMINE (UNII: 903K93S3TK)						
.ALPHATOCOPHEROL ACETAT	E (UNII: 9E8X80D2L0)					
Packaging						
# Itom Codo Da	ckago Description	Ма	rketing Start	Ma	rketing End	

#	item Code	Package Description	Date	Date			
1	NDC:46122-652- 03	1 in 1 CARTON	01/19/2021				
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			
01	C monograph fina	l part346	01/19/2021				

Labeler - Amerisource Bergen (007914906)

Establishment								
Name	Address	ID/FEI	Business Operations					
Inspec Solutions LLC		081030372	manufacture(46122-652)					

Revised: 1/2022

Amerisource Bergen