

LIDOCAINE 5%- lidocaine cream
Apnar Pharma LP

Lidocaine 5% Anorectal Cream

Lidocaine 5% w/w

Local Anesthetic

Uses Temporarily relieves pain and itching due to anorectal disorders

When using this product

- Avoid contact with eyes
- Do not exceed recommended dosage unless directed by a doctor

- Rectal bleeding occurs
- Condition worsens or does not improve within 7 days
- Allergic reaction occurs
- Redness, irritation, swelling, pain or other symptoms begin or increase
- Symptoms clear up and return within a few days

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

DIRECTIONS

- When practical, clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.
- Adults and children 12 years and older: Apply externally to the affected area up to 6 times a day.
- Children under 12 years of age: Consult a doctor

Store at room temperature 20-25°C (68-77°F); Excursions permitted 15-30°C (59-86°F) [see USP Controlled Room Temperature].

Benzyl Alcohol, Carbopol 940 (Carbomer 940), Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine, and Vitamin E Acetate (Alpha Tocopherol Acetate)

DOSAGE

50 milligrams/gram per application

USAGE

Adults and children 12 years and older: Apply externally to the affected area up to 6 times a day.

Children under 12 years of age: Consult a doctor

NDC 24689-124-01

Lidocaine 5% Anorectal Cream

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Net.Wt 30 grams



LIDOCAINE 5%

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24689-124
Route of Administration	RECTAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

WATER (UNII: 059QF0KO0R)

TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24689-124-01	1 in 1 CARTON	11/01/2021	
1		30 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	11/01/2021	

Labeler - Apnar Pharma LP (079568229)

Establishment

Name	Address	ID/FEI	Business Operations
Invaderm		078610697	analysis(24689-124) , manufacture(24689-124) , pack(24689-124)

Revised: 10/2023

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