

**LIDOCAINE ANORECTAL- lidocaine cream**  
**Patrin Pharma Inc.**

*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.*

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**Lidocaine 5% Anorectal Cream**

**Drug Facts**

**Active Ingredient**

Lidocaine 5% w/w

**Purpose**

Local anesthetic

**Uses**

Temporarily relieves pain and itching due to anorectal disorders

**Warnings**

When using this product

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

**Stop use and ask a doctor if**

- 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

**Keep out of reach of children.** 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

**Other information**

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

**Inactive ingredients**

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

**Questions?**

Call 800-936-3088

**PRINCIPAL DISPLAY PANEL - 15 gram Tube Carton**

NDC 39328-025-15

Lidocaine

5%

Anorectal Cream

PATRIN

PHARMA

NET WT. 15 grams



LIDOCAINE ANORECTAL			
lidocaine cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:39328-025
Route of Administration	RECTAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)		Lidocaine	50 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
Benzyl Alcohol (UNII: LKG8494WBH)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)			
Isopropyl Myristate (UNII: 0RE8K4LNJS)			
Polysorbate 80 (UNII: 6OZP39ZG8H)			

<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>Trolamine</b> (UNII: 9O3K93S3TK)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:39328-025-15	1 in 1 CARTON	11/01/2018	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:39328-025-30	1 in 1 CARTON	11/01/2018	
2		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 final	part346	11/01/2018	

**Labeler** - Patrin Pharma Inc. (806841677)

Revised: 4/2022

Patrin Pharma Inc.