

**LIDOCAINE - lidocaine cream**  
**Nivagen Pharmaceuticals, Inc.**

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**Lidocaine 5%**

***Drug Facts***

**Active Ingredient**

Lidocaine 5% w/w

**Purpose**

Topical anesthetic

**Uses**

Temporarily relieves the pain and itching due to anorectal disorders.

**Warnings**

**For external use only.**

**When using this product**

- avoid contact with eyes
- do not use in large quantities, particularly over large surfaces or blistered areas
- do not exceed recommended 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**

- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- allergic reaction occurs to ingredients in this product
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop 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, cleanse the affected 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 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

**Inactive Ingredients**

Verolec HE 60, Benzyl Alcohol, Polysorbate 80, Triethanolamine, Vitamin E- Acetate, Carbomer 940, Isopropyl Myristate, Propylene Glycol, Water

**Questions?**

**1-877-977-0687**

**PRINCIPAL DISPLAY PANEL - 30 g Tube Carton**

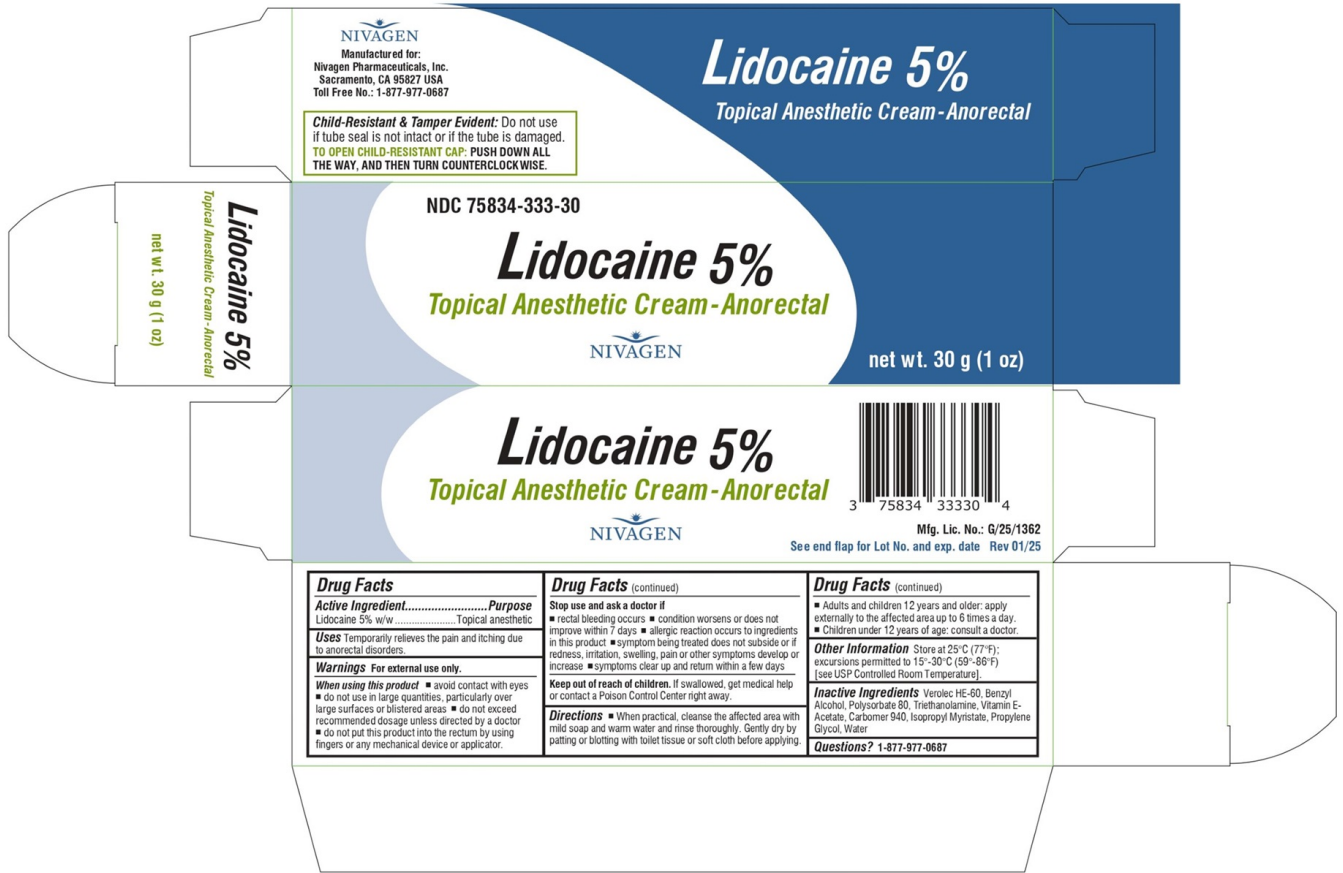
**NDC 75834-333-30**

***Lidocaine 5%***

***Topical Anesthetic Cream-Anorectal***

**NIVAGEN**

**net wt. 30 g (1 oz)**



# LIDOCAINE

lidocaine cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75834-333
<b>Route of Administration</b>	TOPICAL		

## 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
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	

<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CARBOMER 940</b> (UNII: 4Q93RCW27E)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	WHITE (WHITE TO OFF 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:75834-333-30	30 g in 1 TUBE; Type 0: Not a Combination Product	01/05/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M015	01/05/2025	

**Labeler** - Nivagen Pharmaceuticals, Inc. (052032418)

Revised: 1/2025

Nivagen Pharmaceuticals, Inc.