

**LIDOCAINE- lidocaine cream**  
**Nivagen Pharmaceuticals, 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%**

**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°C); excursions permitted to 15°-30°C (59°-86°F) [see USP Controlled Room Temperature].

### **Inactive Ingredients**

benzyl alcohol, carbomer homopolymer type C, C10-18 triglycerides, cholesterol, lecithin, isopropyl myristate, polysorbate 80, propylene glycol, tocopherol, trolamine, water

### **Questions?**

**1-877-977-0687**

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

**NDC 75834-141-30**

***Lidocaine 5%***

***Topical Anesthetic Cream-Anorectal***

**NIVAGEN**

**PHARMACEUTICALS**

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



Nivagen Pharmaceuticals, Inc.  
 Sacramento, CA 95827 USA  
 1-877-977-0687

# Lidocaine 5%

Topical Anesthetic Cream - Anorectal

**Child-Resistant & Tamper Evident:** Do not use if tube seal is not intact or if the tube is damaged.

**To open child-resistant cap:**

Push down and turn counterclockwise.

NDC 75834-141-30

# Lidocaine 5%

Topical Anesthetic Cream - Anorectal



net wt. 30 g (1 oz)

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Topical Anesthetic Cream - Anorectal



See end flap for Lot No. and exp. date Rev 9/17

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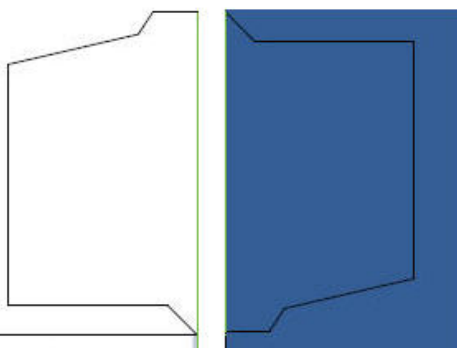
### Drug Facts (continued)

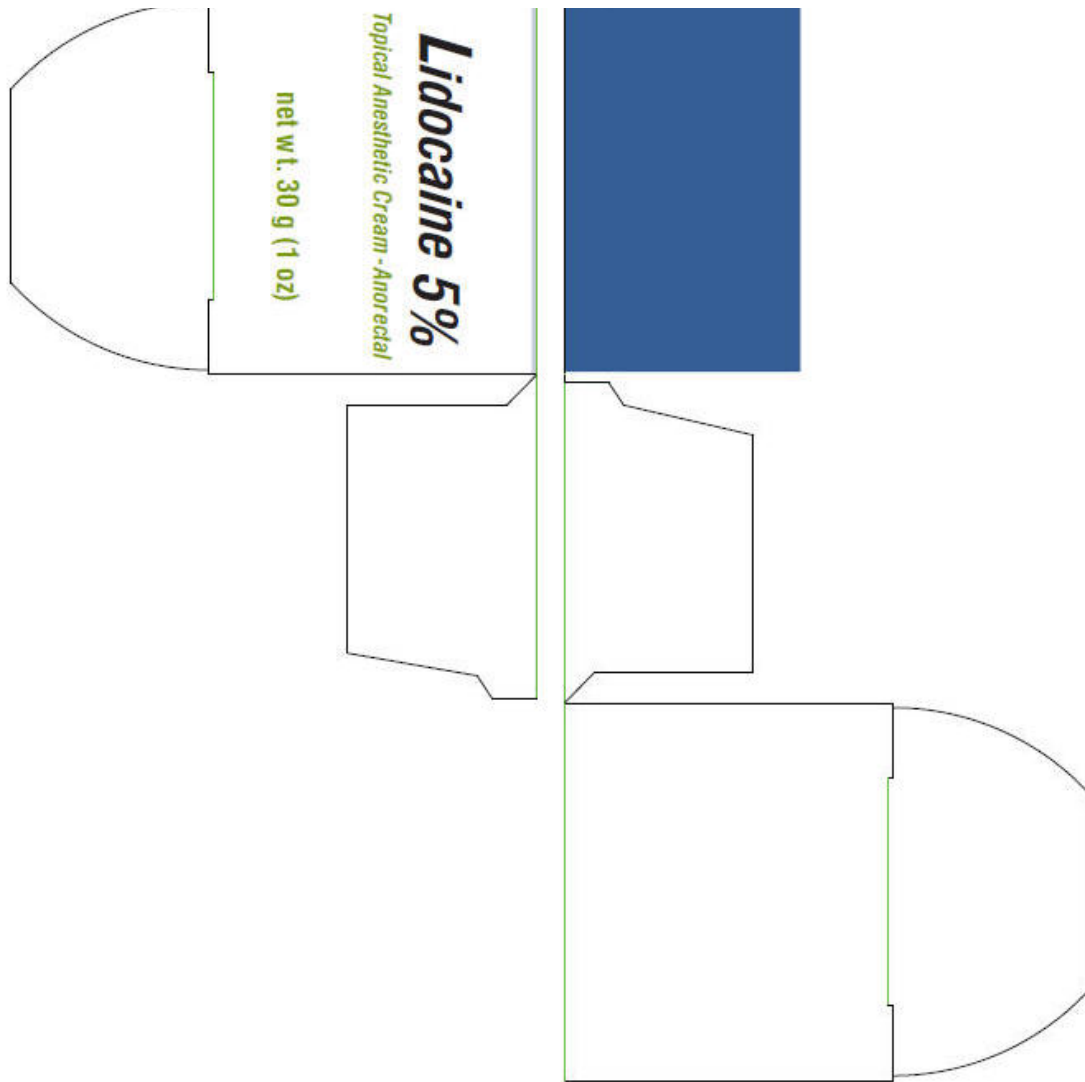
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## LIDOCAINE

lidocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:75834-141
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Lidocaine</b> (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	50 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	

<b>CHOLESTEROL</b> (UNII: 97C5T2UQ7J)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**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:75834-141-30	30 g in 1 TUBE; Type 0: Not a Combination Product	12/15/2016	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	12/15/2016	

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