

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.

Lidocaine 5%

Drug Facts

Active Ingredient

Lidocaine 5% w/w

Purpose

Local anesthetic

Uses

Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.

Warnings

For external use only.

When using this product

- avoid contact with eyes
- 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.
- To use finger cots: Roll one finger cot over finger. Gently squeeze cream onto finger cot. Smooth a layer of the cream over affected area.

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 75834-113-30

***Lidocaine 5%
Anorectal Cream***

Relieves:

- ***Pain***
- ***Itching***
- ***Burning***

**NIVAGEN
PHARMACEUTICALS**

net wt. 30 g (1 oz)

NDC 75834-113-30

Quick

Relief of Pain for
Hemorrhoids & Other
Anorectal Disorders



**Strongest
Non-prescription
Lidocaine Strength
Available**

Lidocaine 5%

Anorectal Cream

10 FINGER COTS INCLUDED

Caution: The Finger Cots Contain Natural Rubber Latex Which May Cause Allergic Reactions

Relieves

Pain Quickly

Lidocaine 5%

Anorectal Cream

NDC 75834-113-30

Lidocaine 5%

Anorectal Cream



Relieves:

- ✓ Pain
- ✓ Itching
- ✓ Burning

net wt. 30 g (1 oz)

Lidocaine 5%

Anorectal Cream



3 75834 11330 2

See end flap for Lot No. and exp. date Rev 8/16

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

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.

Lidocaine 5%

Anorectal Cream

Drug Facts (continued)

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Drug Facts (continued)

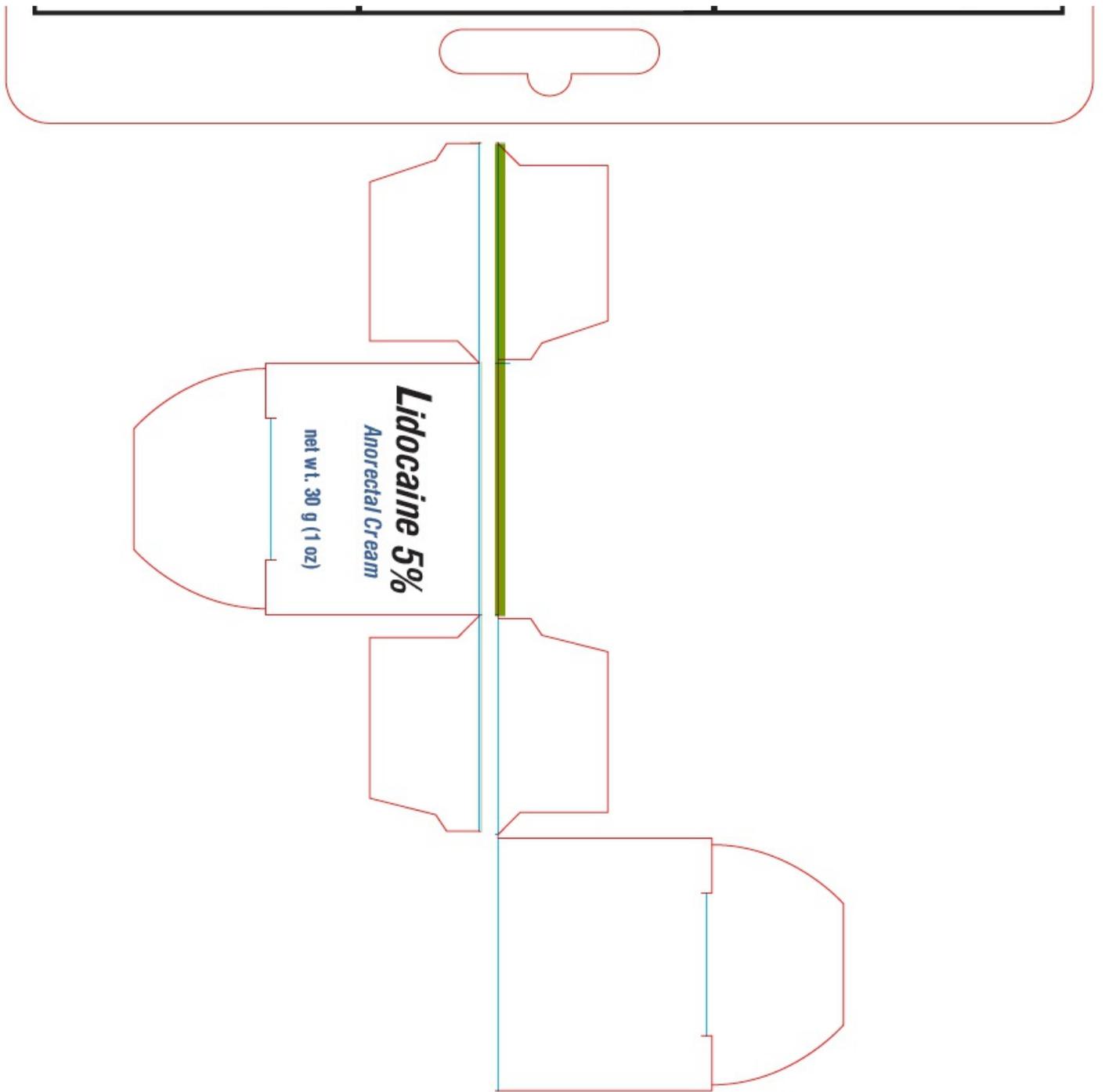
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Purpose.....
Warnings
 ■ anorectal disorders.
 ■ burning associated with hemorrhoids and other anorectal disorders.
 ■ Use Helps relieve the pain, itching, and burning associated with hemorrhoids and other anorectal disorders.
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When using this product
 ■ avoid contact with eyes
 ■ 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.



LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75834-113
Route of Administration	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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75834-113-30	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)

Revised: 1/2020

Nivagen Pharmaceuticals, Inc.