

LIDOCAINE- lidocaine cream
Nivagen Pharmaceuticals, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

NIV35-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



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

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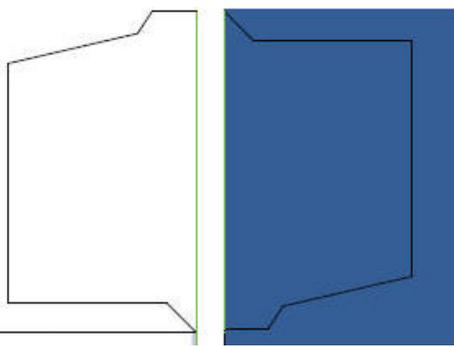
Drug Facts (continued)

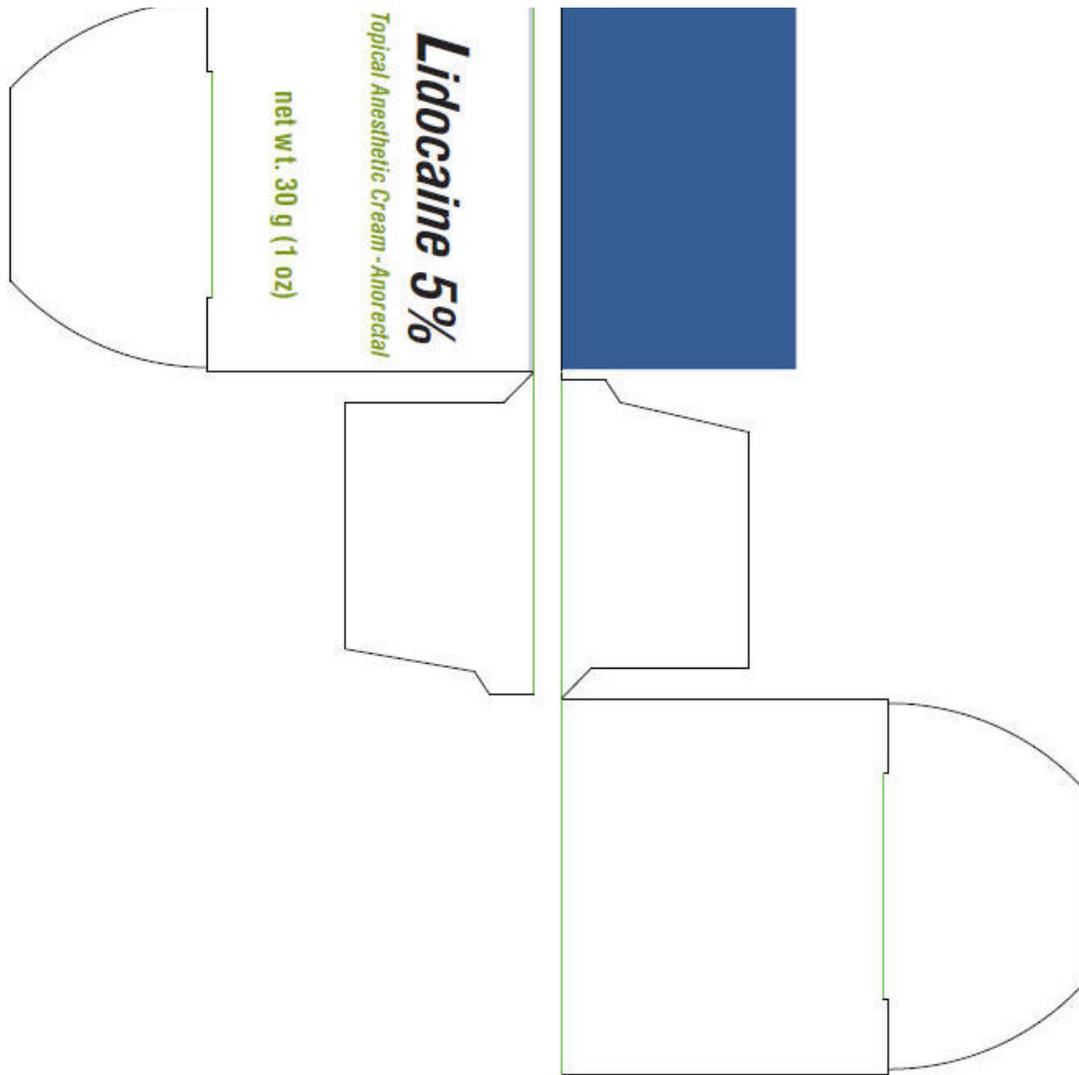
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LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75834-141
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:75834-141-30	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
unapproved drug other		12/15/2016	

Labeler - Nivagen Pharmaceuticals, Inc. (052032418)

Registrant - Westwood Laboratories, LLC (832280635)