

LIDOCAINE- lidocaine cream
Nanjing Cuccess Pharmaceutical Co., Ltd.

Active Ingredients

Lidocaine 4% w/w

Purpose

|Topical anesthetic

Uses

For the temporary relief of pain, itching and burning associated with hemorrhoids and other anorectal disorders.

Warnings

|For external 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
- symptoms 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 USP controlled room temperature 20-25°C (68-77°F).

Inactive ingredient

benzyl alcohol, carbomer homopolymer type C 980NF, cholesterol, isopropyl myristate, polysorbate 80, propylene glycol, purified water, soybean lecithin, tocopherol.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83589-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	1.2 g in 30 g	
Inactive Ingredients				
Ingredient Name			Strength	
BENZYL ALCOHOL (UNII: LKG8494WBH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
TOCOPHEROL (UNII: R0ZB2556P8)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
SOYBEAN LECITHIN (UNII: 1DI56QDM62)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83589-301-01	1 in 1 BOX	04/04/2024	
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:83589-301-03	1 in 1 BOX	04/04/2024	
2		120 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:83589-301-02	1 in 1 BOX	04/04/2024	
3		25 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 Drug	M015	04/04/2024		

Labeler - Nanjing Cuccess Pharmaceutical Co., Ltd. (420793416)

Registrant - Nanjing Cuccess Pharmaceutical Co., Ltd. (420793416)

Revised: 3/2024

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