

PUREGEN LABS MAXIMUM STRENGTH LIDOCAINE- lidocaine cream
Advanced Rx LLC

PUREGEN LABS Maximum Strength Lidocaine 5% Cream

Drug Facts

Active ingredients

Lidocaine 5.00 %

Purpose

Anorectal (hemorrhoidal)

Uses

- Helps relieve the local itching and discomfort in the perianal area
- For the temporary relief of pain, irritation” or burning.

Warnings:

For external use only

Do not

- exceed the recommended daily dosage unless directed by a doctor.
- put this product into the rectum by using fingers or any mechanical device or applicator.

When using this product

- If the condition worsens or does not improve within 7 days, consult a doctor.
- In case of bleeding, consult a doctor promptly.

Stop use and ask a doctor if

- If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase.

Allergy alert

- Certain persons can develop allergic reactions to ingredients in this product.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding,

ask a health professional before use

Directions:

Adults:

- When practical, cleanse the affected area “with mild soap and warm water and rinse by patting or blotting with an appropriate cleansing pad
- Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Children under 12 years of age: consult a doctor.
- Apply externally to the affected area up to 6 times daily or after each bowel movement.

Other information:

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients:

Allantoin, Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Aqua (Deionized Water), Benzyl Alcohol, Carbomer, Dimethyl Isosorbide, Ethylhexylglycerin, Ethylhexyl Stearate, Hydrogenated Polyisobutene, Lecithin, Phenoxyethanol, Propylene Glycol, Sodium Polyacrylate, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Trideceth-6

Questions?

call toll-free **1-800-630-8895**

Package Labeling:



NDC 80513-813-06



1 = 5% CREAM

1) Cream

-VERA

170 g)



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Questions? call toll-free **1-800-630-8895**

Manufactured for:
ADVANCED RX LLC

1942 NE 163rd St. North Miami Beach, FL 33162 U.S.A



PUREGEN LABS MAXIMUM STRENGTH LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-813
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
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
DIMETHYL ISOSORBIDE (UNII: SA6A6V432S)	

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-813-06	170 g in 1 TUBE; Type 0: Not a Combination Product	04/22/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	04/22/2024	

Labeler - Advanced Rx LLC (042795108)

Revised: 4/2024

Advanced Rx LLC