

**LIDOCAINE- lidocaine cream**  
**STRATUS 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% CREAM**

**Drug Facts**

**Active Ingredient**

Lidocaine 5% w/w

**Purpose**

Local anesthetic

**Uses**

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

**WARNINGS**

**"Methemoglobinemia Warning"** use of this product may cause; a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used the product before. Stop use and seek immediate medical attention if the following develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy. If pregnant or breast feeding, ask a health provider before use.

Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center immediately.

**Directions**

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

### Inactive Ingredients

acrylamide, allantoin, aloe vera extract, benzyl alcohol, C12-15 alkyl benzoate, carbomer, isohexadecane, polysorbate 80, propylene glycol, purified water, sodium acryloyldimethyl taurate, sodium laureth sulfate, soy lecithin and tocopheryl acetate.

**Distributed By:** Stratus Pharmaceuticals, Inc., Miami, FL 33186

### PRINCIPAL DISPLAY PANEL - 14.17 g Tube Box

STRATUS  
PHARMACEUTICALS INC

NDC 58980-823-05

Net WT. 0.5 oz. / 14.17 g

LIDOCAINE CREAM  
5%

ANORECTAL CREAM



# LIDOCAINE

lidocaine cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58980-823
<b>Route of Administration</b>	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
ACRYLAMIDE (UNII: 20R035KLCI)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM ACRYLOYLDIMETHYLTAURATE (UNII: 2T9Q6EKI0G)	
SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-823-30	1 in 1 BOX	08/12/2019	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58980-823-05	1 in 1 BOX	12/18/2023	
2		14.17 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			

OTC MONOGRAPH FINAL	part346	08/12/2019	
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**Labeler** - STRATUS PHARMACEUTICALS INC (789001641)

## Establishment

Name	Address	ID/FEI	Business Operations
TARMAC PRODUCTS INC		059890491	MANUFACTURE(58980-823)

Revised: 9/2023

STRATUS PHARMACEUTICALS INC