

**LIDOCAINE- lidocaine cream**  
**Stratus Pharmaceuticals Inc**

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**Lidocaine 3% Cream**

***Drug Facts***

**Active ingredient**

Lidocaine 3% (3g in 100g)

**Purpose**

Local analgesic

**Uses**

for the temporary relief of pain and itching associated with

- minor burns
- sunburn
- minor cuts
- scrapes
- insect bites
- minor skin irritations

**Warnings**

**For external use only**

**When using this product**

- avoid contact with the eyes
- do not use in large quantities, particularly over raw surfaces or blistered areas

**Stop use and consult a doctor if**

- condition worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

Lidocaine is **NOT** approved by FDA to treat teething pain and should **NOT** be given to infants and young children for this use.

**If pregnant or breast-feeding**

Ask a health professional before use.

**Keep out of reach of children.** If accidentally ingested, get medical help or contact a Poison Control Center immediately.

**Directions**

- **Adults and children 2 years of age and older:** Apply to affected area not more than 3 to 4 times daily.
- **Children under 2 years of age:** do not use, consult a doctor.

**Other information**

Store at 20°C to 25°C (68°F to 77°F)

**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, tocopheryl acetate.

**Questions?**

Call us at **(800) 442-7882**

***Distributed by:***

Stratus Pharmaceuticals Inc.  
Miami, FL 33186

**PRINCIPAL DISPLAY PANEL - 85 g Tube Box**

STRATUS  
PHARMACEUTICALS INC

NDC 58980-826-85

Net WT. 3 oz. / 85 g

LIDOCAINE CREAM  
3%

PAIN RELIEVING CREAM

FOR EXTERNAL USE ONLY.  
NOT FOR OPHTHALMIC USE



## LIDOCAINE

lidocaine cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58980-826
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Lidocaine</b> (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	30 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Acrylamide</b> (UNII: 20R035KLCI)	
<b>CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>Allantoin</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>Benzyl Alcohol</b> (UNII: LKG8494WBH)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	

<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM ACRYLOYLDIMETHYLTAURATE</b> (UNII: 2T9Q6EKI0G)	
<b>SODIUM LAURETH-3 SULFATE</b> (UNII: BPV390UAP0)	
<b>SOYBEAN LECITHIN</b> (UNII: 1DI56QDM62)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58980-826-30	1 in 1 BOX	02/15/2024	
1		28.35 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58980-826-85	1 in 1 BOX	07/01/2025	
2		85 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	M017	02/15/2024	

**Labeler** - Stratus Pharmaceuticals Inc (789001641)

### Establishment

Name	Address	ID/FEI	Business Operations
Tarmac Products Inc		059890491	MANUFACTURE(58980-826)

Revised: 6/2025

Stratus Pharmaceuticals Inc