

LIDOCAINE- lidocaine cream
Stratus Pharmaceuticals Inc

Lidocaine 4% Cream

Drug Facts

Active ingredient

Lidocaine 4% (4g 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 - 28.35 g Tube Box

STRATUS
PHARMACEUTICALS INC

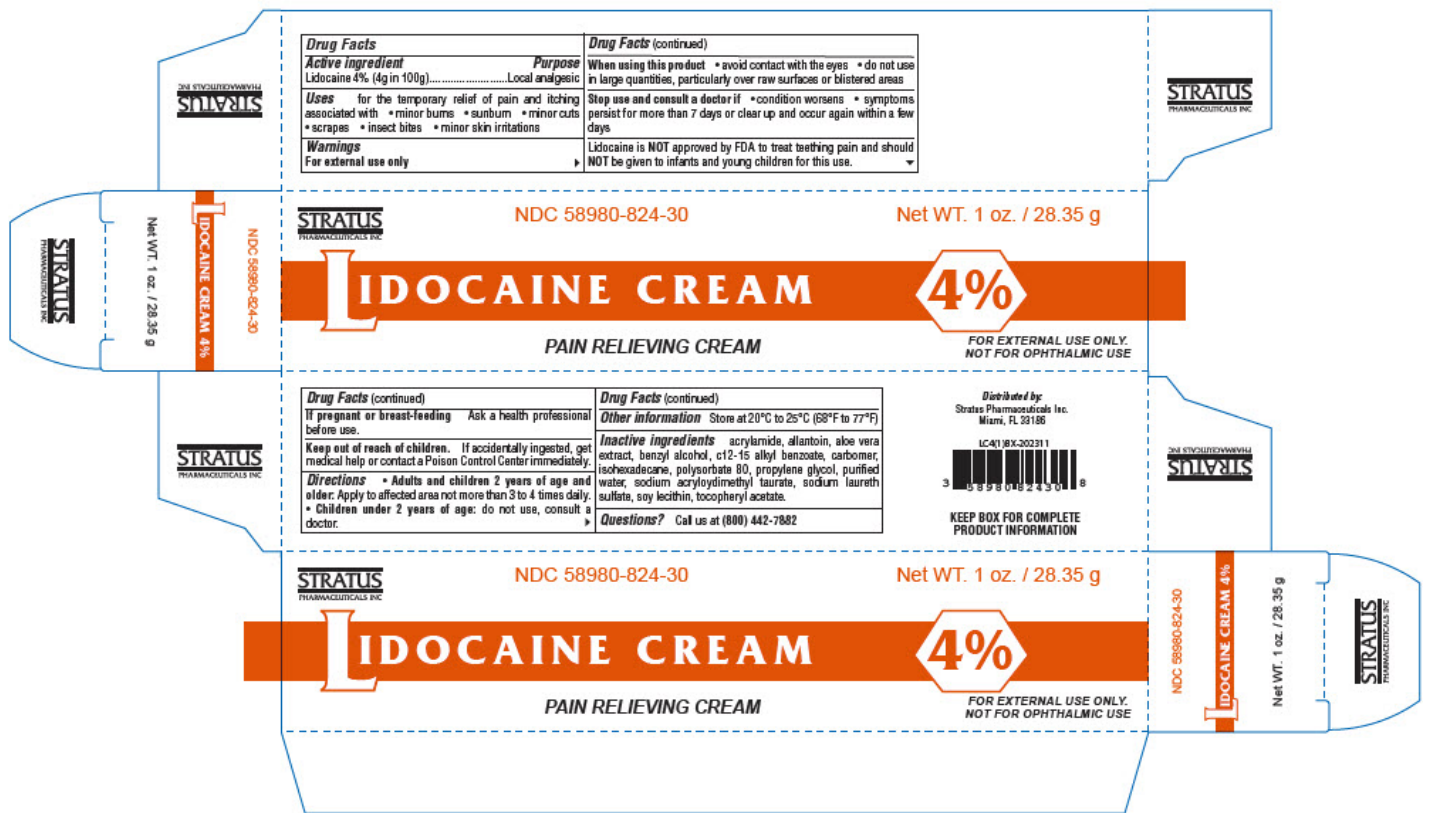
NDC 58980-824-30

Net WT. 1 oz. / 28.35 g

LIDOCAINE CREAM
4%

PAIN RELIEVING CREAM

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE



LIDOCAINE

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-824
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (Lidocaine - UNII:98PI200987)	Lidocaine	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Acrylamide (UNII: 20R035KLCI)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
Allantoin (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
Benzyl Alcohol (UNII: LKG8494WBH)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOHEXADECANE (UNII: 918X10UF1E)	
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:58980-824-30	1 in 1 BOX	02/15/2024	
1		28.35 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(58980-824)

Revised: 1/2024

Stratus Pharmaceuticals Inc