

LIDOCAINE- lidocaine cream
STRATUS PHARMACEUTICALS INC

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

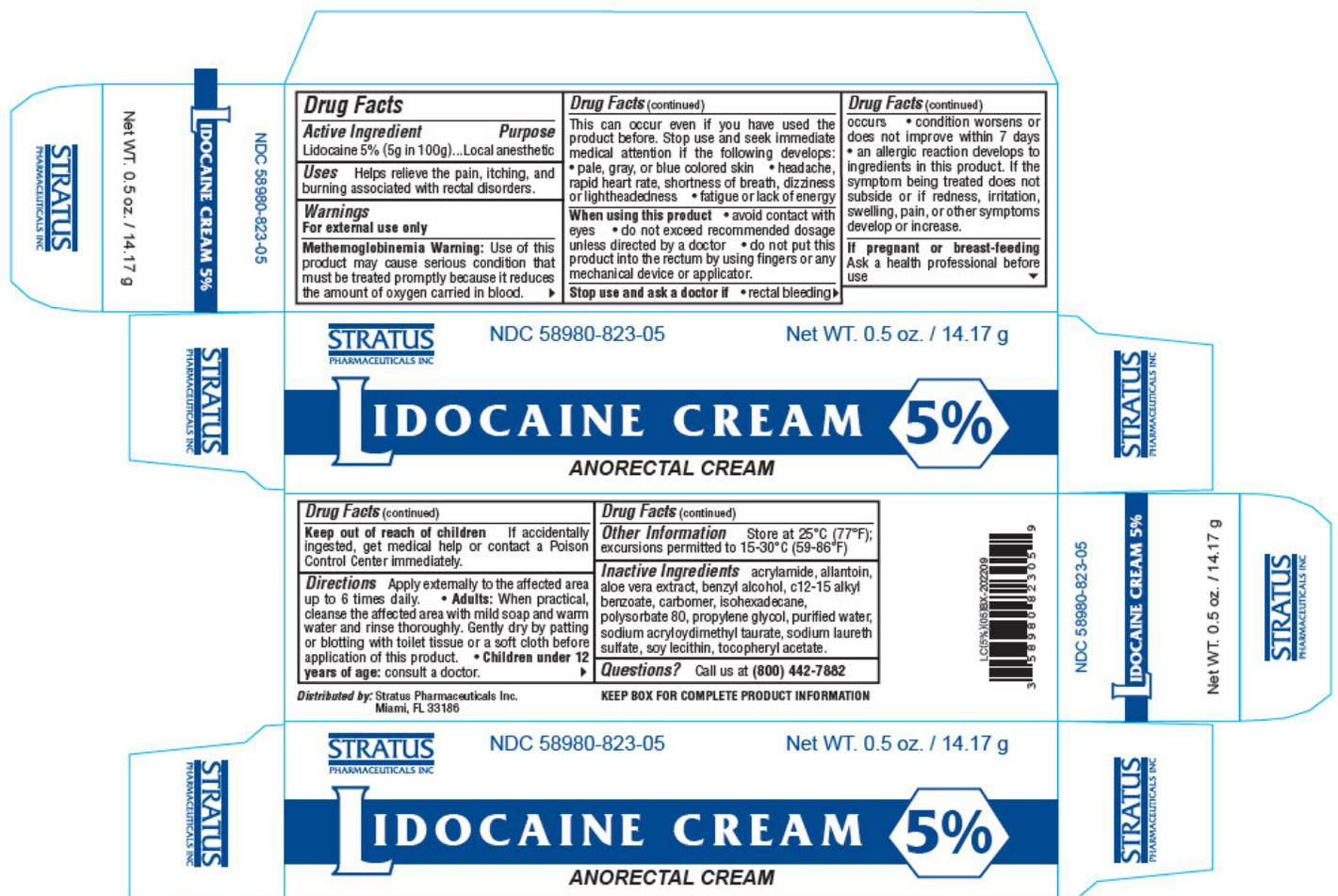
STRATUS
PHARMACEUTICALS INC

NDC 58980-823-05

Net WT. 0.5 oz. / 14.17 g

LIDOCAINE CREAM
5%

ANORECTAL CREAM



LIDOCAINE
lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58980-823
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
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)	
SOYBEAN LECITHIN (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 drug	M017	08/12/2019	

Labeler - STRATUS PHARMACEUTICALS INC (789001641)

Establishment

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

Revised: 11/2024

STRATUS PHARMACEUTICALS INC