LIDOCAINE 4% CREAM- lidocaine cream
Rugby Laboratories

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.

Lidocaine 4% Cream

DESCRIPTION

Lidocaine 4% cream is a non-greasy cream specially formulated with soothing agents, indicated as a topical anesthetic for use on normal intact skin for local analgesia and itching due to minor cuts, minor scrapes, sunburn, minor skin irritations, minor burns and insect bites.

INGREDIENTS

ACTIVE: Lidocaine (4%)

INACTIVE

Butylated Hydroxytoluene, Cetostearyl Alcohol, Citric Acid, Edetate Disodium, Light Mineral Oil, Methylparaben, Polyoxyl 20 Cetostearyl Ether, Propylene Glycol, Propylparaben, Purified Water, Sodium Citrate and White Petrolatum.

MECHANISM OF ACTION

Lidocaine 4% cream applies to intact skin provides dermal analgesia by the release of lidocaine from the cream into the epidermis and dermis. Lidocaine is a local anesthetic agent of the amide type. Local anesthetics reversibly block the initiation and conduction of nerve impulses by interfering with the flux of sodium ions through the neuronal membrane. The onset, depth and duration of dermal analgesia provided depend upon the site and duration of application.

INDICATIONS AND USAGE

Lidocaine 4% cream is indicated for use on normal intact skin for temporary relief of pain and itching due to minor cuts, minor scrapes, minor skin irritations, minor burns and insect bites.

Lidocaine 4% cream is not recommended for internal use, in the or near the eyes and in large quantities, particularly over raw surfaces or blistered areas.

CONTRAINDICATIONS

Lidocaine 4% cream is contraindicated in patients with sensitivity to amide type local anesthetics or to any component of the product.

WARNINGS

For external use only. Avoid contact with the eyes. Do not use over large areas of the body. Do not use for more than seven days unless directed by a doctor. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Inappropriate use of this product, such as on large areas of the body, application on mucous membranes, or on individuals that are allergic to the amide type anesthetics, may result in serious side effects. Consultation with a doctor before using this product is strongly recommended.

PRECAUTIONS

Repeated doses of lidocaine 4% cream may increase blood levels of lidocaine. Avoid contact with the eyes. If eye contact occurs, immediately wash out the eye with water or saline.

The patient should be aware that dermal analgesia may be accompanied by the block of all sensations in the treated skin. For this reason, the patient should avoid inadvertent trauma to the treated area by scratching, rubbing or exposure to extreme hot or cold temperatures until complete sensation has returned.

DRUG INTERACTIONS

Lidocaine 4% cream should be used with caution in patients receiving Class I antiarrhythmic agents (e.g., tocainide, mexiletine) since the toxic effects are potentially additive and synergistic.

- **Adults and children 2 years and older**. Apply externally to the affected area up to 3 to 4 times a day.
- **Children under 2 years of age**. Consult a doctor.

HOW SUPPLIED

NDC 0536-1281-28 (30 gram tubes)

Store at USP controlled room temperature 20° to 25°C (68° to 77°F).

Manufactured by:
Teligent Pharma, Inc.
Buena, New Jersey 08310

Distributed by:
RUGBY® LABORATORIES
17177 N. Laurel Park Dr., Suite 233
Livonia, MI 48152

Revised 01/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rugby®

NDC 0536-1281-28

Lidocaine Cream 4%

Net Wt. 30 grams

For Topical Use Only
Do Not Use in the Eyes

LIDOCAINE 4% CREAM

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1281
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	4 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Citric Acid Acetate (UNII: DSO12WL7AU)	
Edetate Disodium Anhydrous (UNII: 8NLQ36F6MM)	
Light Mineral Oil (UNII: N6K5787QVP)	
Methylparaben (UNII: A2I8C7HI9T)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Propylparaben (UNII: Z8IX2SC1OH)	

Water (UNII: 059QF0KO0R)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
Petrolatum (UNII: 4T6H12BN9U)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1281-28	1 in 1 CARTON	03/13/2020	
1		30 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 not final	part348	03/13/2020	

Labeler - Rugby Laboratories (079246066)

Establishment

Name	Address	ID/FEI	Business Operations
Teligent, Inc.		011036910	manufacture(0536-1281)

Revised: 3/2020 Rugby Laboratories