

## **LIDOCAINE 4% CREAM- lidocaine cream** **Teligent Pharma, 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.*

-----

### **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.

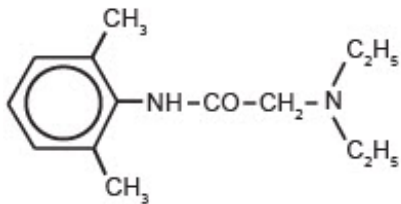
#### **INGREDIENTS**

**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.

The chemical designation of Lidocaine is 2-(diethylamino)-N(2,6-dimethylphenyl), acetamide. The structure of lidocaine is:



#### **MECHANISM OF ACTION**

Lidocaine 4% cream applied 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.

## **DIRECTIONS**

- **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 52565-122-07 (5 x 5 gram tubes)

NDC 52565-122-15 (15 gram tubes)

NDC 52565-122-30 (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

PI-122-01

Revised 09/2018

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 52565-122-15

Lidocaine Cream 4%

Net Wt. 15 grams

For Topical Use Only

Do Not Use in the Eyes

**NDC 52565-122-15**

**Lidocaine Cream 4%**

Net Wt. 15 grams

For Topical Use Only  
Do Not Use in the Eyes

<b>Drug Facts</b>	<b>Active ingredient Purpose</b> Lidocaine 4.0%... anesthetic
<b>Uses</b>	Temporarily relieves pain due to: • sunburns • minor burns • insect bites • minor cuts • minor skin scratches • irritations
<b>Warnings</b>	For external use only. Do not use in large quantities, particularly over raw surfaces or blistered areas.
<b>When using this product</b>	• keep out of eyes • use only as directed.
<b>Stop use and ask doctor if</b>	• action gets worse • symptoms last more than 7 days • symptoms clear up and occur again in a few days.
<b>Keep out of reach of children.</b>	If swallowed, get medical help or contact a Poison Control Center right away.
<b>Directions</b>	• 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: ask a doctor.
<b>Inactive ingredients</b>	butylated hydroxytoluene, cetearyl alcohol, citric acid, edetate disodium, light mineral oil, methylparaben, polyoxy 20 cetearyl ether, propylene glycol, propylparaben, purified water, sodium citrate, and white petrolatum.
<b>Questions?</b>	Call Teligent Pharma, Inc. at 1-866-697-1441. Manufactured by: Teligent Pharma, Inc. 105 Boulevard Buena, NJ 08310

**NDC 52565-122-15**

**Lidocaine Cream 4%**

Net Wt. 15 grams

For Topical Use Only  
Do Not Use in the Eyes

To open, push down on cap while turning counter-clockwise and lift off.  
Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].  
See crimp of tube for Lot No. and Exp. Date

**Teligent**

Manufactured by:  
Teligent Pharma, Inc.  
Buena, New Jersey 08310  
C100920 Rev. 09/2018

3 52565 12215 5

# LIDOCAINE 4% CREAM

lidocaine cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52565-122
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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: YRC528SWJY)	
Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
Petrolatum (UNII: 4T6H12BN9U)	
Propylene Glycol (UNII: 6DC9Q167V3)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52565-122-07	5 in 1 CARTON	01/22/2019	
1		5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:52565-122-15	1 in 1 CARTON	01/22/2019	
2		15 g in 1 TUBE; Type 0: Not a Combination Product		

3	NDC:52565-122-30	1 in 1 CARTON	01/22/2019	
3		30 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348		01/22/2019	

**Labeler** - Teligent Pharma, Inc. (011036910)

### Establishment

Name	Address	ID/FEI	Business Operations
Teligent, Inc.		011036910	manufacture(52565-122)

Revised: 1/2019

Teligent Pharma, Inc.