

## Safety Data Sheet

### Lidocaine and prilocaine Cream USP, 2.5%/2.5%

Strength: 2.5 %

Pack Size: 5gm and 30 gm

NDC 72578-165-05

Revision No.: 00

NDC 72578-165-06

#### Emergency Overview

Lidocaine and prilocaine cream USP, 2.5%/2.5% is an emulsion in which the oil phase is a eutectic mixture of lidocaine and prilocaine in a ratio of 1:1 by weight. This eutectic mixture has a melting point below room temperature and therefore both local anesthetics exist as a liquid oil rather than as crystals.

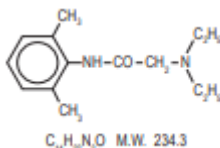
#### Section 1: Identification

**Product Name:** Lidocaine 2.5% and Prilocaine 2.5% Cream

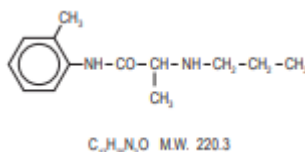
**Formula of Lidocaine:** C<sub>14</sub>H<sub>22</sub>N<sub>2</sub>O

**Prilocaine:** C<sub>13</sub>H<sub>20</sub>N<sub>2</sub>O

**Chemical Name of Lidocaine:** Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)



**Prilocaine:** Propanamide, N-(2-methylphenyl)-2-(propylamino)



**Molecular Weight of Lidocaine:** 234.3

**Molecular Weight of Prilocaine:** 220.3

**Description:** Lidocaine and prilocaine cream USP, 2.5%/2.5% is an emulsion in which the oil phase is a eutectic mixture of lidocaine and prilocaine in a ratio of 1:1 by weight. This eutectic mixture has a melting point below room temperature and therefore both local anesthetics exist as a liquid oil rather than as crystals. It is packaged in 5 gram and 30gram tubes.

#### Manufacturer / supplier identification

**Company Address**

**M/S. ZYDUS LIFESCIENCES LIMITED**  
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Pharmaceutical.

**Section 2: Hazard (s) Identification****Dose and Administration****Adult Patients-Intact Skin**

A thick layer of lidocaine and prilocaine cream is applied to intact skin and covered with an occlusive dressing

(see INSTRUCTIONS FOR APPLICATION).

**Minor Dermal Procedures**

For minor procedures such as intravenous cannulation and venipuncture, apply 2.5 grams of lidocaine and prilocaine cream (1/2 the 5 g tube) over 20 cm<sup>2</sup> to 25 cm<sup>2</sup> of skin surface for at least 1 hour. In controlled clinical trials using lidocaine and prilocaine cream, two sites were usually prepared in case there was a technical problem with cannulation or venipuncture at the first site.

**Adult Male Genital Skin**

As an adjunct prior to local anesthetic infiltration, apply a thick layer of lidocaine and prilocaine cream (1 g/10 cm<sup>2</sup>) to the skin surface for 15 minutes. Local anesthetic infiltration should be performed immediately after removal of lidocaine and prilocaine cream.

Dermal analgesia can be expected to increase for up to 3 hours under occlusive dressing and persist for 1 hour to 2 hours after removal of the cream. The amount of lidocaine and prilocaine absorbed during the period of application can be estimated from the information in Table 2, \*\* footnote, in **Individualization of Dose.**

**Adult Female Patients-Genital Mucous Membranes**

For minor procedures on the female external genitalia, such as removal of condylomata acuminata, as well as for use as pretreatment for anesthetic infiltration, apply a thick layer (5 grams to 10 grams) of lidocaine and prilocaine cream for 5 minutes to 10 minutes.

Occlusion is not necessary for absorption, but may be helpful to keep the cream in place. Patients should be lying down during the lidocaine and prilocaine cream application, especially if no occlusion is used. The procedure or the local anesthetic infiltration should be performed immediately after the removal of lidocaine and prilocaine cream.

**Pediatric Patients-Intact Skin**

The following are the maximum recommended doses, application areas and application times for lidocaine and prilocaine cream based on a child's age and weight.

<b>Age and Body Weight Requirements</b>	<b>Maximum Total Dose of Lidocaine and Prilocaine Cream</b>	<b>Maximum Application Area</b>	<b>Maximum Application Time</b>
0 up to 3 months or < 5 kg	1 g	10 cm <sup>2</sup>	1 hour
3 up to 12 months and > 5 kg	2 g	20 cm <sup>2</sup>	4 hour
1 year to 6 years and > 10 kg	10 g	100 cm <sup>2</sup>	4 hour
7 years to 12 years and > 20 kg	20 g	200 cm <sup>2</sup>	4 hour

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Please note: If a patient greater than 3 months old does not meet the minimum weight requirement, the maximum total dose of lidocaine and prilocaine cream should be restricted to that which corresponds to the patient's weight (see **INSTRUCTIONS FOR APPLICATION**).

Practitioners should carefully instruct caregivers to avoid application of excessive amounts of lidocaine and prilocaine cream (see **PRECAUTIONS**).

When applying lidocaine and prilocaine cream to the skin of young children, care must be taken to maintain careful observation of the child to prevent accidental ingestion of lidocaine and prilocaine cream or the occlusive dressing. A secondary protective covering to prevent inadvertent disruption of the application site may be useful.

**Lidocaine and prilocaine cream should not be used in neonates with a gestational age less than 37 weeks nor in infants under the age of 12 months who are receiving treatment with methemoglobin-inducing agents (see Methemoglobinemia subsection of WARNINGS).**

When lidocaine and prilocaine cream (lidocaine 2.5% and prilocaine 2.5%) is used concomitantly with other products containing local anesthetic agents, the amount absorbed from all formulations must be considered (see Individualization of Dose). The amount absorbed in the case of lidocaine and prilocaine cream is determined by the area over which it is applied and the duration of application under occlusion (see Table 2, \*\* footnote, in **Individualization of Dose**).

Although the incidence of systemic adverse reactions with lidocaine and prilocaine cream is very low, caution should be exercised, particularly when applying it over large areas and leaving it on for longer than 2 hours. The incidence of systemic adverse reactions can be expected to be directly proportional to the area and time of exposure (see **Individualization of Dose**).

## Adverse effects

### Localized Reactions

During or immediately after treatment with lidocaine and prilocaine cream on intact skin, the skin at the site of treatment may develop erythema or edema or may be the locus of abnormal sensation. Rare cases of discrete purpuric or petechial reactions at the application site have been reported. Rare cases of hyperpigmentation following the use of lidocaine and prilocaine cream have been reported. The relationship to lidocaine and prilocaine cream or the underlying procedure has not been established. In clinical studies on intact skin involving over 1,300 lidocaine and prilocaine cream-treated subjects, one or more such local reactions were noted in 56% of patients, and were generally mild and transient, resolving spontaneously within 1 hour or 2 hours. There were no serious reactions that were ascribed to lidocaine and prilocaine cream. Two recent reports describe blistering on the foreskin in neonates about to undergo circumcision. Both neonates received 1 g of lidocaine and prilocaine cream.

In patients treated with lidocaine and prilocaine cream on intact skin, local effects observed in the trials included: paleness (pallor or blanching) 37%, redness (erythema) 30%, alterations in temperature sensations 7%, edema 6%, itching 2% and rash, less than 1%.

In clinical studies on genital mucous membranes involving 378 lidocaine and prilocaine cream-treated patients, one or more application site reactions, usually mild and transient, were noted in 41% of patients. The most common application

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site reactions were redness (21%), burning sensation (17%) and edema (10%).

#### Allergic Reactions

Allergic and anaphylactoid reactions associated with lidocaine or prilocaine can occur. They are characterized by urticaria, angioedema, bronchospasm and shock. If they occur they should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

#### Systemic (Dose Related) Reactions

Systemic adverse reactions following appropriate use of lidocaine and prilocaine cream are unlikely due to the small dose absorbed (see **Pharmacokinetics** subsection of **CLINICAL PHARMACOLOGY**). Systemic adverse effects of lidocaine and/or prilocaine are similar in nature to those observed with other amide local anesthetic agents including CNS excitation and/or depression (light-headedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest). Excitatory CNS reactions may be brief or not occur at all, in which case the first manifestation may be drowsiness merging into unconsciousness. Cardiovascular manifestations may include bradycardia, hypotension and cardiovascular collapse leading to arrest.

### Section 3: Composition / information on ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Lidocaine	137-58-6	Lignocaine	C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> O	234.3	2.5%
Prilocaine	721-50-6	Propanamide, N-(2-methylphenyl)-2-(propylamino)-	C <sub>13</sub> H <sub>20</sub> N <sub>2</sub> O	220.3	2.5%

### Section 4: First -aid measures

#### Ingestion:

If a person vomits place them in the recovery position so that vomit will not Reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

#### Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20

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minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

#### Signs and Symptoms:

Cream is intended for topical use only under guidance of a physician. Cream is not considered hazardous under normal conditions.

#### Medical Conditions Aggravated by Exposure:

No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes.

#### Other Health Warnings:

For topical use only.

#### Notes to Physician:

Treat supportively and symptomatically.

### Section 5: Fire -fighting measures

#### Suitable extinguishing media:

Use water, carbon dioxide, dry chemical or foam as necessary.

#### Unsuitable extinguishing Media:

With small quantities use carbon dioxide extinguisher. For large fires use ample quantities of water with dry chemicals or foam as necessary.

#### Specific Hazards Arising from the Chemical:

#### Hazardous Combustion Products:

Not determined.

#### Other Specific Hazards:

Not determined.

#### Special Protective Equipment/Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

### Section 6: Accidental Release Measures

#### Personal precautions:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

#### Methods for Cleaning Up:

Pick up in the most efficient manner. Soak up with sawdust, sand oil dry or other absorbent material.

#### Environmental Precautions:

No data available.

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Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Storage**

Keep container tightly closed and store between 59°F – 86°F. Store according to label and/or product insert information.

**Section 8: Exposure controls/personal protection****Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Lidocaine	STEL: 5 mg/m <sup>3</sup> TWA: 1 mg/m <sup>3</sup>
Prilocaine	STEL: 5 mg/m <sup>3</sup> TWA: 1 mg/m <sup>3</sup>

**Engineering Controls:**

Not required for the normal use of this product. Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:**

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:**

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:**

Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:**

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

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### Section 9: Physical and chemical properties

#### Physical and Chemical Properties

<b>Physical State/Color:</b>	White to off-white smooth cream.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	9.0 – 9.4.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	Same as water.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	>1.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### Section 10: Stability and reactivity

<b>Reactivity:</b>	No data available.
<b>Chemical stability:</b>	Stable under recommended storage conditions. Avoid source of ignition.
<b>Possibility of hazardous Reactions:</b>	No data available.
<b>Conditions to avoid ( e.g. static Discharge, sock, or vibration):</b>	No data available.
<b>Incompatible materials:</b>	Strong Oxidizer.
<b>Hazardous decomposition Products:</b>	Does not undergo explosive decomposition.
<b>Hazardous Polymerization:</b>	Will not occur.

### Section 11: Toxicological information

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##### Information on the Likely Routes of Exposure:

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<b>Inhalation:</b>	No data available.
<b>Ingestion:</b>	No data available.
<b>Skin Contact:</b>	No data available.
<b>Eye Contact:</b>	No data available.

#### Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### Delayed and Immediate Effects of Exposure:

No data available.

<b>Acute Toxicity – Oral:</b>	No data available.
<b>Acute Toxicity – Dermal:</b>	No data available.
<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	No data available.
<b>Eye Irritation:</b>	No data available.
<b>Sensitization:</b>	No data available.
<b>Toxicokinetic/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	No data available.
<b>Reproductive Effects:</b>	No data available.
<b>Carcinogenicity:</b>	No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on  
Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health  
Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.  
**Aspiration Hazard:** No data available

## Section 12: Ecological information

### Ecotoxicity

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bio accumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

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**Section 13: Disposal consideration**

**Waste Disposal Methods**

Dispose in accordance with all local, state and federal regulations.

**Section 14: Transport information**

**UN Number:**

Not applicable.

**UN Proper Shipping Name:**

Not applicable.

**Transport Hazard Class(es):**

Not applicable.

**Packing Group:**

Not applicable.

**Department of Transportation:**

Not regulated as a hazardous material.

**International Air Transport Association (IATA):**

Not regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):**

Not regulated as a dangerous good.

**Section 15: Regulatory information**

**US Federal Regulations:**

**Toxic Substance Control Act (TSCA):**

Not listed.

**CERCLA Hazardous Substance and Reportable Quantity:**

Not listed.

**SARA 313:**

Not listed.

**SARA 302:**

Not listed.

**State Regulations**

California Proposition 65: Not listed.

**Section 16: Other information**

**NFPA Rating:** Health = 0

Flammability = 1

Reactivity = 0

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

**Date of issue:** 13/07/24

**Supersedes edition:** N/A