

**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
 PRFTPT-011**

**1 GENERAL PRODUCT INFORMATION**

Lidocaine 2% with Epinephrine in its different concentrations and commercial dosage forms is an anesthetic solution for injection (subcutaneous small volume) for dental use, indicated to produce local anesthesia, applied the techniques by infiltration or nerve block. This product should be used by personnel with professional certification, trained to perform dental procedures.

**1.1 Commercial Name and International Nonproprietary Name (INN)**

Lidocaine 2% with Epinephrine E-50  
 Lidocaine 2% with Epinephrine E-80  
 Lidocaine 2% with Epinephrine E-100  
 Newcaine 2%® : Lidocaine 2% with Epinephrine 1: 50 000  
 Newcaine 2%® : Lidocaine 2% with Epinephrine 1: 80 000

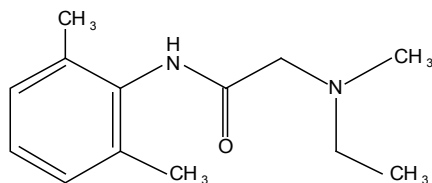
Systematic IUPAC Names:

Epinephrine: (R)-4-[ 1-hydroxy-2-(methylamino)ethyl ] benzene-1,2-diol

Lidocaine: Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl) -2-(diethylamino)- 2'6'-acetylidine.

**1.2 Structural Formula, Molecular Formula, and/or Empiric Formula of Active Ingredients:**

**LIDOCAINE**



**Molecular Formula** C<sub>14</sub>H<sub>22</sub>N<sub>2</sub>O

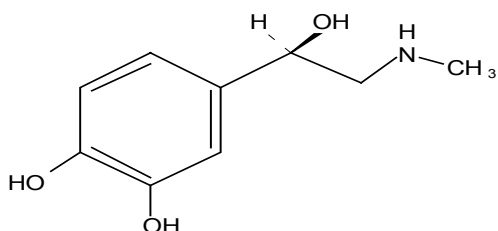
<b>Created</b>		<b>Prepared by:</b>		<b>Verified by:</b>	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
<b>Class</b>	<b>Page</b>	<b>Approved by</b>		<b>Updated</b>	<b>Version</b>
E	1 de 14	Anesthetics Technical Director		2019-05-13	3

**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
 PRFTPT-011**

<b>Molecular Mass</b>	234.34 g/mol
-----------------------	--------------

IUPAC Name: Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-2-(diethylamino)-2'6'-acetoxyldine (CASH 137-58-6)

**EPINEPHRINE**



<b>Molecular Mass</b>	183.21 g/mol
-----------------------	--------------

IUPAC Name: (R)-4-(1-hydroxy-2-(methylamino)ethyl)benzene-1,2-diol (CASH 51-43-4).

**2 INFORMATION ABOUT COMPOSITION ELEMENTS**

Each dental cartridge of 1.8 ml.-contains:

Lidocaine with epinephrine 1:50.000 (Lidocaine 2% E-50)  
 Lidocaine Base: 0.036 g  
 Epinephrine Base: 0.000036 g  
 Excipients q.s. a.d.: 1.8 ml

Lidocaine with epinephrine 1:80.000 (Lidocaine 2% E-80)  
 Lidocaine Base: 0.036 g  
 Epinephrine Base: 0.0000225 g  
 Excipients q.s. a.d.: 1.8 ml

<b>Created</b>		<b>Prepared by:</b>		<b>Verified by:</b>	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
<b>Class</b>	<b>Page</b>	<b>Approved by</b>		<b>Updated</b>	<b>Version</b>
E	2 de 14	Anesthetics Technical Director		2019-05-13	3



## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

Lidocaine with epinephrine 1:100.000 (Lidocaine 2% E-100)  
Lidocaine Base: 0.036 g  
Epinephrine Base: 0.000018 g

Excipients q.s. a.d.: 1.8 ml

### 3 PROPERTIES OF THIS PRODUCT

To exert its anesthetic action, Lidocaine stabilizes the neuronal membrane by inhibiting the ionic fluxes required for the initiation and conduction of nerve impulses. Epinephrine causes local vasoconstriction which restricts the absorption of the anesthetic, prolongs its action and diminishes its systemic toxicity.

Lidocaine stabilizes the neuronal membrane by inhibiting the ionic fluxes required to initiate and transmit the nerve impulses (**see figure N° 1**), leading to its local anesthetic effects. It has a rapid, deep, and extended anesthetic action. It allows the dentist to work in the most delicate dental procedures such as preparation of stumps in live teeth, pulpsectomies, and surgical treatment of periodontitis.

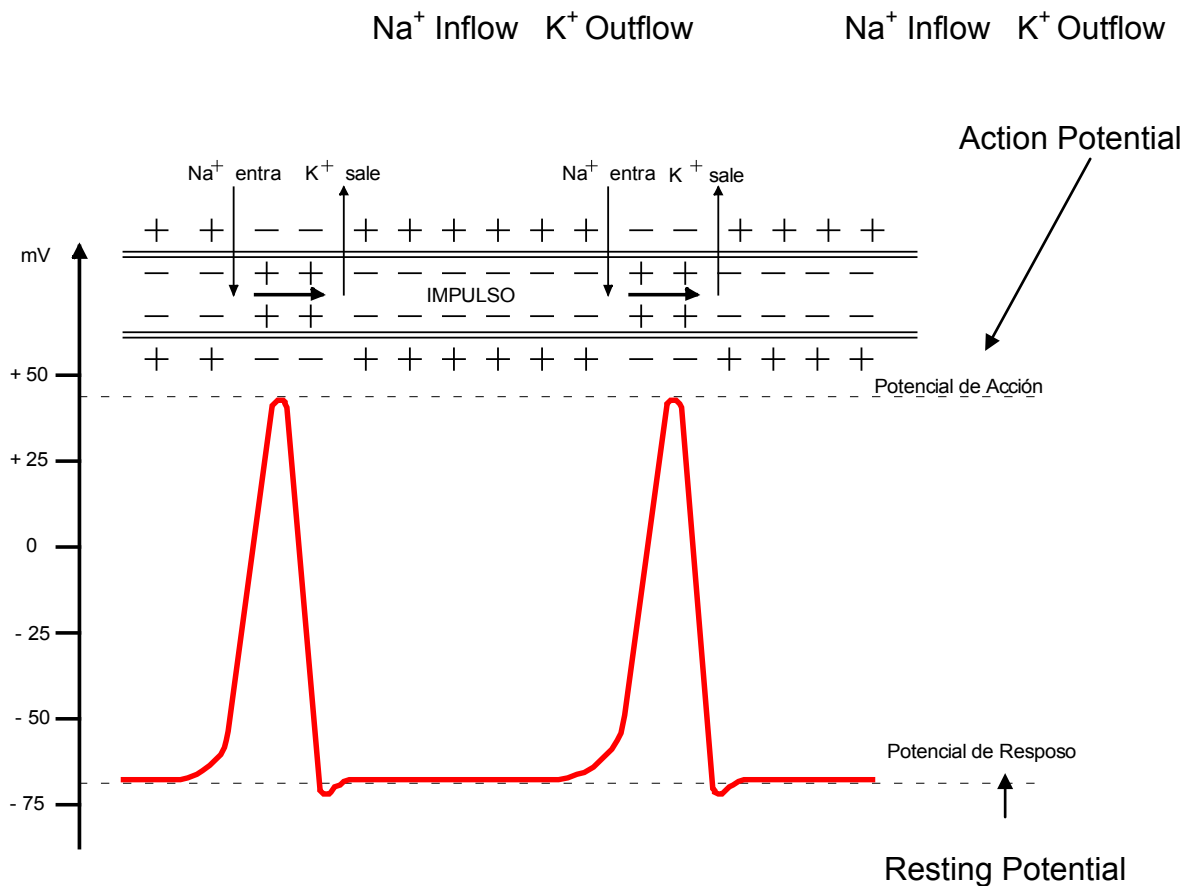
The anesthetic action of Lidocaine is more than two times greater than that of Procaine. In equal concentration, the intensity of the anesthetic effect of Lidocaine as well the area in which it exerts its action are two times greater than those of Procaine.

Due to its amino amide chemical structure which makes it so different than the structure of Procaine and other related-local anesthetics, Lidocaine can be the right anesthetic for those people who are sensitive to Procaine. Lidocaine is completely atoxic and [adverse drug reactions](#) (ADRs) are rare when lidocaine is used as a local anesthetic and is administered correctly.

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	3 de 14	Anesthetics Technical Director		2019-05-13	3

**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
 PRFTPT-011**

**Figure N° 1**  
**Changes in polarity and action potential in the conduction of impulses by a nervous fiber**



**3.1 METABOLISM**

<b>Created</b> 2010-01-12		<b>Prepared by:</b> Pharmaceutical Analyst		<b>Verified by:</b> Anesthetics Quality Assurance Coordinator	
<b>Class</b> E	<b>Page</b> 4 de 14	<b>Approved by</b> Anesthetics Technical Director		<b>Updated</b> 2019-05-13	<b>Version</b> 3



## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

Approximately 90% of Lidocaine is metabolized in the **liver** and is eliminated in the form of various metabolites through the kidneys. Only 10% of this substance is excreted without alteration

Epinephrine is rapidly inactivated in the human body. The human liver produces two enzymes for the destruction of circulating epinephrine. The action of liver is important but it is not indispensable in the degradation process of lidocaine. Most part of this substance is excreted in metabolites with urine

### 4 USAGE AND APPLICATIONS

Lidocaine 2% with Epinephrine is a local anesthetic that is suitable for infiltration and nerve block anesthesia. The Epinephrine supplement delays the resorption and lengthens the anesthetic action of Lidocaine which must be longer for some dental procedures

#### 4.1 WARNINGS

Facilities for resuscitation should be immediately available when administering local anesthetics, in order to provide good aeration and ventilation in case of possible toxic reactions.

Intravascular injections of small doses of local anesthetics into the head and the neck may produce systemic adverse reactions similar to those observed in cases of accidental intravascular injections at higher doses.

In patients with acidosis or hypoxia, the risk and severity of toxic reactions may be increased. Such reactions involve the Nervous Central System (CNS) and the Cardiovascular System. Local anesthetics must be used with caution in patients with anemia, severe cardiovascular diseases or circulatory dysfunctions of any kind. The effect of local anesthetics may be reduced if the injection is made into an inflamed or abscessed area.

Solutions of local anesthetics which contain a vasoconstrictor agent must be used with caution and according to the prescribed dose.

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	5 de 14	Anesthetics Technical Director		2019-05-13	3



## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

These solutions should not be injected into distal sites of the body because the ischemia that is produced can lead to a gangrene. In dental procedures, a vasoconstrictor should not be repeatedly injected into the same area because it reduces the blood flow and increases the oxygen consumption in the affected tissues which can lead to tissue anoxia, cicatricial delay of the edema or necrosis at the injection site

### 4.2 PRECAUTIONS

Crossed sensitivity and /or other related problems are rare when amide-type local anesthetics are used

Pregnancy: Animal studies have revealed no evidence of harm to the fetus. However, local anesthetics may cause constriction of the uterine artery

Amide-type local anesthetics are metabolized in the liver. This is why these anesthetics must be used with caution in patients with hepatic failure

### 4.3 CONTRA-INDICATIONS

Local anesthetics should be avoided in cases of regional ischemia, hepatic failure, renal disease or hypersensitivity to lidocaine

Lidocaine is contra-indicated in patients suffering from known hypersensitivity to all amide-type local anesthetics and also in case of shock or heart block.

To obtain local anesthesia, Lidocaine should not be injected into an inflamed or infected area. Lidocaine is not intended for use intravenously in patients with Stokes-Adams Syndrome or severe second or third degree intra-ventricular, atrio-ventricular or sinoatrial heart block

The use of commercial solutions of Lidocaine which contain sulfites increases the risk of anaphylactic or bronchospastic reactions. A harmful cardiac stimulation may appear in patients with hyperthyroidism

Excessive doses of this local anesthetic may lead to high blood plasma concentrations followed by depression of the cardiovascular system (hypotension, bradycardia,

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	6 de 14	Anesthetics Technical Director		2019-05-13	3



## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

arrhythmias, unusual paleness, increased perspiration and/or cardiac arrest), toxicity of the Central Nervous System (blurred or double vision, confusion, convulsions, dizziness or daze, sensations of heat/cold, shiver, anxiety, excitation, nervousness or restlessness)

### 4.4 ADVERSE DRUG REACTION

**Adverse drug reactions** (ADRs) are rare when Lidocaine 2% with Epinephrine is used as a local anesthetic and is employed correctly in dental procedures. If some adverse reactions appear, they have similar characteristics to those produced by other local anesthetics

**Adverse reactions** are generally produced by high blood plasma concentrations caused by excessive doses, fast or inadvertent intravascular injections or may be due to an idiosyncratic hypersensitivity or a diminished tolerance to local anesthetics on the part of the patient. Usually, a stimulation of the Central Nervous System does not appear before depression of this system

**CNS reactions** may be excitatory and/or depressant and may manifest as nervousness, dizziness, blurred vision, tremor, followed by restlessness, convulsions, unconsciousness, and possible respiratory arrest. Cardiovascular reactions are depressant and may manifest as hypotension, myocardial depression, bradycardia, and possible cardiac arrest

Allergic reactions are rare. They may be characterized by late cutaneous lesions, urticaria, edema or other anaphylactoid reactions. They can also produce tingling and numbness of lips and mouth (also known as circumoral paraesthesia)

### 4.5 TREATMENT IN CASE OF OVERDOSAGE

The following will be the management of local anesthetic emergencies in case of overdose.

Lie the patient face up; lift the patient's legs up (30°- 45°) from his/her resting-position; if ventilation is not adequate, provide assisted or controlled ventilation with oxygen if possible.

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	7 de 14	Anesthetics Technical Director		2019-05-13	3



## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

If the pulse rate of patient is low (<40) or not shown, standard cardiopulmonary resuscitation procedures should be instituted, for example, an external cardiac massage. If the patient is unconscious and /or the ventilation is inadequate in spite of the afore-mentioned supportive measures, begin a treatment of convulsions and apply mechanic ventilation.

**Convulsions:** The first step in the management of convulsions consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen. Efforts must be made in order to stop convulsions. Should convulsions persists despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as. Sodium Thiopental (50-100 mg, increased) every 2 or 3 minutes) or a benzodiazepine (such as diazepam, 25 mg, increased) may be administered intravenously in order to stop convulsion, keeping in mind that barbiturates may also depress the circulation when injected intravenously.

The clinician should be familiar, prior to use local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, a vasopressor as directed by the clinical situation (e.g., ephedrine).

This treatment may also involve the risk of respiratory depression. Facilities for providing or controlling mechanical ventilation should be available

Neuromuscular blockers can also be used to decrease persistent convulsions. Artificial respiration is compulsory when using neuromuscular blockers

**Methemoglobinemia:** If methemoglobinemia does not stop after applying adequate oxygenation, an intravenous injection of a solution at 1% of methylene blue (1-2 mg per kg of body weight (mg/kg) for a period of 5 minutes is suggested.

**Allergic** reactions such as cutaneous lesions, urticaria, edema or other anaphylactoid reactions are rare. These symptoms must be treated with conventional therapy

### 4.6 INTERACTIONS WITH DRUGS OR DRUG-RELATED PROBLEM

Interactions of Lidocaine with anti-arrhythmic agents may result in additive cardiac effects; with anticonvulsants of the Hidantoine group, Lidocaine causes heart depression and is metabolized more rapidly. The use of adrenergic beta-blockers may

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	8 de 14	Anesthetics Technical Director		2019-05-13	3





**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
PRFTPT-011**

increase the toxicity of Lidocaine. The use of cimetidine may increase the levels of Lidocaine in the blood plasma

Neuromuscular blockers may increase their effect if used simultaneously with Lidocaine. The use of Lidocaine can interfere with certain lab tests : Bentiromide test results may be altered ; Cimetidine-phosphokinase (cpk) test values may increase in case of intramuscular injections of lidocaine

The use of sympathomimetic vasoconstrictors such as epinephrine may cause additive toxicity. The risk of a significant systemic effect resulting from the interactions of some of the following drugs with a vasoconstrictor agent contained in an anesthetic solution depends on the total dose (volume and concentration) of the administered vasoconstrictor and on factors that affect the absorption average of the vasoconstrictor agent (site and route of administration, and the potential of the intravascular injection

The efficacy of the vasoconstrictor agent may be diminished by the use of adrenergic alpha-blockers such as Labetalol, Phenoxybenzamine, Phentolamine, Prazosin, thioxantenes, or rapidly-acting vasodilators such as nitrates

Patients who receive epinephrine, levonordephrine or norepinephrine but not phenylephrine, the alpha-adrenergic block may become a beta-adrenergic activity with risk of hypotension and severe tachycardia

Vasoconstrictor agents may diminish the therapeutic effects of vasodilator agents, including the effects of nitrates against chest angina.

Hydrocarbon anesthetics (chloroform, cyclopropane, halotane or trichloroethylene and to a much lesser degree, euflurane, isoflurane or metoxyflurane), may sensitize the heart for the effects of a sympathomimetic vasoconstriction; If they are associated with a vasoconstrictor agent, a cardiac arrhythmia may happen

Tricyclic antidepressants or maprotilene in combination with lidocaine may increase the cardiovascular effects of a vasoconstrictor agent and, as a result of this, cardiac arrhythmias, tachycardia, severe hypertension or hyperpyrexia may happen

**Antihypertensors or diuretics used as antihypertensors:** The hypertensors' effects may diminish because of the vasoconstrictor agent (It is highly recommended to control blood pressure).

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	9 de 14	Anesthetics Technical Director		2019-05-13	3



## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

### 4.7 DRUG INCOMPATIBILITIES

The administration of a solution of a local anesthetic which contains epinephrine to patients who are receiving treatment with drugs that produce alteration in their blood

pressure (e.g. monoaminoxidase (MAO) inhibitors, tricyclic antidepressants, or phenothiazines) can lead to a prolonged hypotension or hypertension

Lidocaine hydrochloride associated with amphotericin causes precipitation, and is occasionally incompatible (depending on the pH and the vehicle) with ampicillin sodium

The concomitant use of a vasopressor agent and oxytocic drugs such as ergotamine may cause persistent hypertension or cerebrovascular accidents

No incompatibilities of Lidocaine with food have been found

### 5 QUALITY ASSURANCE AND CONTROL

Lidocaine 2% with Epinephrine is manufactured under the most strict technical and quality controls. Its manufacturing process is carried out in special manufacture areas with environmental, microbiological, and operational controls made by specially trained employees. Raw materials used in this product are previously examined and approved according to requirements of pharmacopeias currently into effect. The control process includes the control of Blister Packing and secondary packaging materials. All raw materials are furnished by qualified providers

In its different presentations, the product Lidocaine 2% with Epinephrine conforms to all requirements established for this product by current pharmacopeias and regulating agencies. These specifications include appearance of product, physical properties, contents of active ingredients, and microbiological controls. All these parameters are verified during the different steps of the manufacturing process with the use of high technology equipment, standardized procedures, areas for special analysis, and specially trained employees

### 6 INSTRUCTIONS FOR USE

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	10 de 14	Anesthetics Technical Director		2019-05-13	3



**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
PRFTPT-011**

Lidocaine 2% (20 mg/ml; 36 mg/1.8 ml) with Epinephrine, in its different concentrations and according to medical prescriptions, can be used as follows

**Adult Patients:** The maximum dose for healthy adults should not exceed 6.6 mg/kg of body weight or 300 mg per dental procedure

**Pediatric Patients:** Pediatric doses must be established according to each individual by the dental professional, according to the patient's age and weight.

If the purpose is to administer this local anesthetic to pediatric patients in concentrations that are lower than the existing commercial concentrations, we advise to proceed as follows: Dilute the commercial concentration in the amount of sodium chloride at 9% that is necessary to obtain the final concentration of the local anesthetic that will be injected

The dosage of the local anesthetic depends upon the following aspects: physical condition of patient, area of the oral cavity that will be anesthetized, vascularity of the oral tissues, and the technique of anesthesia that will be employed

The dentist should use the lowest dose of the anesthetic solution that can provide the desired anesthetic effect. The patient should be carefully monitored for possible adverse reactions

Anesthetic solutions which contain epinephrine can be used in those oral procedures in which a longer effect of lidocaine is required in the injection site. Patients with decrease of hepatic blood flow or hepatic failure may require a lesser dose of lidocaine or a longer interval between doses

Special cases to be taken into account

**Injections into Infected Areas:**

The buffer capacity of tissues will normally cause a stabilization of pH at the level of the tissue. Injections into infected areas will sometimes result in incomplete anesthesia

because the infected focus produces residual acids that normally reduce the buffer capacity of tissues. An acid pH will reduce the anesthetic power of an injected solution

<b>Created</b>		<b>Prepared by:</b>		<b>Verified by:</b>	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
<b>Class</b>	<b>Page</b>	<b>Approved by</b>		<b>Updated</b>	<b>Version</b>
E	11 de 14	Anesthetics Technical Director		2019-05-13	3



**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
PRFTPT-011**

**Anatomic Variations:** In some patients, injections may fail due to a deviated position of the nerve or to an exceptionally thick and compact bone that constitutes a barrier for the diffusion and will make an injection through infiltration technique less effective

**Intravenous Injections:** If all or the most part of the anesthetic solution is injected intravascularly, there will be a poor anesthetic effect or not at all. Some adverse

sympathomimetic effects (tachycardia, hypertension) as well an increase of the characteristic toxicity of the local anesthetic may occur.

**Very Rapid Injections:** Excessive pressure during an injection may cause local irritation and postoperative pains. A very rapid injection may also cause necrosis of palate tissues due to the firmness of the ligament on the bone

**Disinfection of cartridges:** Local anesthetic cartridges must not be submerged in solutions made of anticorrosive tablets or in solutions of quaternary ammonium salts such as benzalkonium chloride. Some metal ions (e.g. mercury, zinc, copper) are contained in disinfectant solutions and may be the cause of inflammations after anesthetic procedures. This is why local anesthetic cartridges should not be submerged into these solutions

For the chemical disinfection of the cartridge surface, it is advisable to use isopropyl alcohol at 91% or ethylic alcohol at 70% without denaturalizing agents. Solutions which contain heavy metals are not recommended

Lidocaine 2% with Epinephrine should not be used if the solution is colored (pink or brownish colors) or if it contains a precipitate

The anesthetic solution Lidocaine 2% with Epinephrine must not be submitted to autoclave sterilization because of the thermal decomposition of epinephrine (thermolability)

Any amount of anesthetic solution that remains in the cartridge must be discarded

Created		Prepared by:		Verified by:	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
Class	Page	Approved by		Updated	Version
E	12 de 14	Anesthetics Technical Director		2019-05-13	3

## TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE PRFTPT-011

### 7 COMMERCIAL PRESENTATIONS OF THIS PRODUCT

The anesthetic solution Lidocaine 2% with Epinephrine is marketed in the following commercial packagings.

#### Primary Packaging

Glass Cartridges : Cylindrical ampoules made of type I- glass (Borosilicate glass)

Cartridges : Cylindrical ampoules made of virgin polypropylene

Both types of commercial primary packaging have the same sliding plug and top cap  
 Natural-rubber plug and metallic top cap with diaphragm (aluminium and natural rubber)

#### Secondary Packaging

Two types of commercial secondary packaging are available

Blister in cardboard box per 50 cartridgees

Plastic Box por 50 cartridgees



<b>Created</b>		<b>Prepared by:</b>		<b>Verified by:</b>	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
<b>Class</b>	<b>Page</b>	<b>Approved by</b>		<b>Updated</b>	<b>Version</b>
E	13 de 14	Anesthetics Technical Director		2019-05-13	3



Dirección: Cra. 53 N° 50-09  
Guarne (Antioquia) COLOMBIA.  
Teléfono: (574) 550 00 00  
Fax: (574) 551 31 34

**TECHNICAL DATA SHEET: LIDOCAINE 2% WITH EPINEPHRINE  
PRFTPT-011**

**8. EXPIRATION DATE**

Two (2) years.

**8 STORAGE AND CONSERVATION MEASURES**

The injectable solution Lidocaine 2% with Epinephrine must be stored in dry and cool areas, away from direct heat and light or intense light sources. It should be stored at a temperature below 30° C. (111,6°F).

<b>Created</b>		<b>Prepared by:</b>		<b>Verified by:</b>	
2010-01-12		Pharmaceutical Analyst		Anesthetics Quality Assurance Coordinator	
<b>Class</b>	<b>Page</b>	<b>Approved by</b>		<b>Updated</b>	<b>Version</b>
E	14 de 14	Anesthetics Technical Director		2019-05-13	3

DOCUMENTO DE REFERENCIA: DPDDPR-019  
VERSIÓN: 0