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TECHNICAL DATA SHEET LIDOCAINE 2% WITH EPINEPHRINE 1:80.000 SP
DPFTPT-136

1. PRODUCT OVERVIEW

1.1. Brand name

Lidocaine 2% E80

1.2. Generic name

Lidocaine Hydrochloride 2% with Epinephrine 1:80.000 injectable solution

1.3. Dosage form

Injectable solution

1.4. Description

Lidocaine 2% E80 is an injectable solution for dental use that contains as active ingredients Lidocaine Hydrochloride in a 2% concentration as generator of the anesthetic effect and Epinephrine base in a 0.0125% concentration as a vasoconstrictor.

Lidocaine Hydrochloride is an amide-type anesthetic agent that provides extremely rapid, deep, and extensive anesthesia. It allows to work in the most delicate procedures such as the preparation of stumps in living teeth, pulpectomies and the surgical treatment of periodontitis. Epinephrine, on the other hand, acts as a vasoconstrictor, allowing to enhance anesthetic effects, increase the duration of the effect and decrease the permeability of the product at the systemic level.

2. COMPOSITION INFORMATION

2.1. Active pharmaceutical ingredients

The active ingredients of the product Lidocaine 2% with Epinephrine 1:80,000 are described below:

COMPONENT	CONCENTRATION	QUANTITY PER CARTRIDGE 1,8 mL
Lidocaine Hydrochloride	20 mg/mL	36 mg
Epinephrine	0,0125 mg/mL	0,0225 mg

2.2. Non-active pharmaceutical ingredients

The excipients of the product Lidocaine 2% with Epinephrine 1:80,000 are described below:

COMPONENTS
Sodium Metabisulfite
Sodium Chloride
Disodium Edetate
Hydrochloric Acid
Water for Injection

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3. PRODUCT PROPERTIES

3.1. Physico-chemical properties

PROPERTIES	VALUE
Appearance	Clear solution, Colorless
Odor	Odorless
Stage	Liquid
Volume	1,8 mL
Density	~ 1,0 g/cm^3
Viscosity	~ 1,0 cp
Solubility	Very Soluble
Boiling point	~ 80 °C
Melting point	~ 0 °C

3.2. Pharmacological properties

Pharmacological properties

Pharmacotherapeutic group: Nervous system / Local Anesthetics / Anesthetics / Amides / Lidocaine, combinations, ATC cod: N01BB52.

Mechanism of Action and Pharmacodynamic Effects: Lidocaine Hydrochloride, an amide local anesthetic, reversibly blocks nerve conduction through a known mechanism that has been commonly observed with other amide local anesthetics. This consists of the decrease or prevention of the large transient increase in the permeability of excitable membranes to sodium (Na^+), which is normally produced by a slight depolarization of the membrane. This produces an anesthetic action. As the anesthetic action progressively develops in the nerve, the threshold of electrical excitability gradually increases, the rate of action potential rise decreases, and impulse conduction slows. Epinephrine, as a vasoconstrictor, acts directly on both α-adrenergic and β-adrenergic receptors. Epinephrine prolongs the duration of effect of Lidocaine Hydrochloride and reduces the risk of excessive uptake in the systemic circulation.

Clinical efficacy and safety: Used as a dental anesthetic, Epinephrine solutions have a latency time of 1 to 3 minutes, a duration of pulpal anesthesia of 90 minutes and 3.5 hours. in soft tissues.

Pharmacokinetics properties

Absorption: Peak plasma levels of Lidocaine 2% with Epinephrine 1:80,000 after perioral injections of combined Epinephrine solutions during dental procedures were determined in various clinical studies. Cmax is 1.9 mg/ml Lidocaine Hydrochloride after injection of 160 mg Lidocaine Hydrochloride.

Distribution: The binding of Lidocaine Hydrochloride to plasma proteins is dependent on the concentration of the drug and the bound fraction decreases with increasing concentration. At concentrations between 1 and 4 µg of free fraction per mL, between 60 and 80% of Lidocaine Hydrochloride is protein bound. Binding

is also dependent on the plasma concentration of α-1-acid glycoprotein (AAG). Lidocaine Hydrochloride crosses the blood-brain and placental barriers, presumably by passive diffusion.

Biotransformation: Lidocaine Hydrochloride is rapidly metabolized by the liver by the cytochrome P480 system, metabolites and unmetabolized drug are excreted by the kidneys. Biotransformation includes oxidative N-dealkylation, aromatic hydroxylation, amide bond cleavage, and conjugation. N-dealkylation produces the metabolites monoethylglycinexylidide and glycinexylidide. The pharmacological/toxicological actions of these metabolites are similar, but less potent than those of Lidocaine Hydrochloride. Approximately 90% of administered Lidocaine Hydrochloride is excreted as various metabolites and less than 10% is excreted unchanged. The primary metabolite in urine is a 4-hydroxy-2, 6-dimethylaniline conjugate.

Elimination: Studies of the metabolism of Lidocaine Hydrochloride after intravenous bolus injection have shown that the elimination half-life of this agent is between 1.5 and 2 hours. Due to the high rate of metabolism of Lidocaine Hydrochloride, any condition that affects liver function can alter the kinetics of Lidocaine Hydrochloride. The half-life may be prolonged twice or more in patients with hepatic dysfunction. Renal dysfunction does not affect the kinetics of Lidocaine Hydrochloride, but may increase the accumulation of metabolites.

4. USES AND APLICATIONS

4.1. Indications

Local and loco-regional anesthesia in dental procedures. Lidocaine Hydrochloride 2% with Epinephrine 1:80,000 is indicated in adults, adolescents and children.

4.2. Posology

As with any local anesthetic, doses vary depending on the area of anesthesia, the vascularization of the tissues, the number of nerve segments to be blocked, the tolerance of the individual (degree of muscle relaxation and the patient's condition) and the technique and depth of anesthesia. The lowest dose that produces efficient anesthesia should be used. The necessary dose must be determined individually.

The maximum recommended dose of Lidocaine Hydrochloride is 7 mg/kg body weight for a healthy 70 kg adult. The total dose injected in all areas, distributed in a dental session, must not exceed the absolute maximum dose of 800 mg of Lidocaine Hydrochloride or 0.2 mg of Epinephrine, whichever is the lesser of both amounts. Therefore, the dose of epinephrine is the limiting dose whatever the weight.

Pediatric patients.

Special caution should be exercised when treating children under 4 years of age. The amount to be injected should be determined by the age and weight of the child and the extent of the operation. The anesthesia technique must be chosen meticulously. Painful anesthesia techniques should be avoided. The behavior of children during treatment must be carefully supervised.

The average dose to be used is in the range of 20 mg to 30 mg of Lidocaine Hydrochloride per session. The mean dose in mg of Lidocaine Hydrochloride that can be administered to children can be calculated by multiplying the child's weight (in kilograms) by 1.33.

The equivalent of 5 mg of Lidocaine Hydrochloride per kilogram of body weight should not be exceeded.

Special populations

Due to lack of clinical data, special care should be taken to administer the lowest dose that produces effective anesthesia in patients older than 70 years and in patients with renal or hepatic insufficiency.

4.3. Interactions

Interactions with Lidocaine Hydrochloride.

- Other anesthetics:

Lidocaine Hydrochloride should be used with caution in patients treated concomitantly with other products for local anesthesia, since the toxic effects are additive (risk of overdose).

The total dose of Lidocaine Hydrochloride administered should not exceed the maximum recommended dose.

- Opioid sedatives*:*

In case of concomitant administration, reduced doses of Lidocaine 2% with Epinephrine 1:80,000 should be used due to the possible additive depressant effect on the central nervous system of Lidocaine Hydrochloride and sedatives.

- CYP1A2 inhibitors:

Lidocaine Hydrochloride is primarily metabolized by the CYP1A2 enzyme. Inhibitors of this cytochrome (eg, ciprofloxacin, enoxacin, fluvoxamine) may decrease its metabolism, increase the risk of adverse effects, and contribute to prolonged or toxic blood levels of Lidocaine Hydrochloride. Increased serum levels of amide anesthetics have also been reported after concomitant administration of cimetidine, probably due to the inhibitory effect of cimetidine on CYP1A2.

- Nonselective β-adrenergic blocking agents:

They can increase plasma concentrations of Lidocaine Hydrochloride by reducing hepatic blood flow and inhibiting CYP1A2. Caution should be exercised when Lidocaine Hydrochloride and non-selective β-blockers are administered concomitantly. Nonselective β-adrenergic blocking agents may also potentiate the vasopressor effects of Epinephrine.

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Interactions with Epinephrine:

- Postganglionic adrenergic blocking agents*:*

They inhibit the uptake of catecholamines and/or increase the responsiveness of target tissues. Reduced doses should be used under close medical supervision followed by meticulous aspiration due to the risk of hypertension and other cardiovascular effects of epinephrine.

- Tricyclic antidepressants or drugs that combine an adrenergic and serotonergic effect.

Block reuptake of catecholamines from sympathetic nerve terminals.

- MAO inhibitors and/or catechol-O-methyl transferase (COMT) inhibitors:

They inhibit the metabolism of catecholamines.

- Non-selective beta-adrenergic blocking agents*:*

They block the β vasodilator component of epinephrine, leaving an α-adrenergic vasoconstrictor effect unopposed. Non-selective β-adrenergic agents may also increase the plasma concentration of Lidocaine Hydrochloride.

- Sympathomimetic vasopressors and other sympathomimetics:

There is a risk of adrenergic toxicity. If cocaine has been taken in the last 24 hours, planned dental treatment should be postponed.

- Ergot-type oxytocic drugs:

Use under strict medical supervision due to additive or synergistic increases in blood pressure and/or ischemic response.

- Halogenated volatile anesthetics:

Potentiation of the dysrhythmic potential of catecholamines. The patient's hemodynamic status should be closely monitored.

- Antiarrhythmics:

May cause additive arrhythmogenic effects Meticulous aspiration prior to administration and cardiovascular monitoring (ECG) recommended.

- Phenothiazines and other neuroleptics:

They block the α-adrenergic activity of Epinephrine. Use under strict medical supervision and cardiovascular monitoring is recommended in patients with hypotension.

4.4. Overdose

The term local anesthetic overdose is often used in a broad sense to describe:

- Absolute overdose
- Relative overdose
  - Accidental injection into a blood vessel
  - Abnormal rapid absorption into the systemic circulation
  - Delayed drug metabolism and elimination

In case of relative overdose, patients usually develop symptoms within a few minutes. In contrast, in the case of absolute overdose, signs of toxicity appear some time after injection, depending on the injection site. Following an overdose (absolute or relative), since arousal may be transient or absent, the first manifestation may be drowsiness, progressing to unconsciousness and respiratory arrest.

Symptoms due to Lidocaine Hydrochloride:

Symptoms are dose dependent and progressive in severity in the range of neurological manifestations (presyncope, syncope, headache, restlessness, agitation, confusional state, disorientation, dizziness, tremor, stupor, profound CNS depression, loss of consciousness, coma, convulsions, speech disturbances, vertigo, balance disturbances), ocular manifestations (mydriasis, blurred vision, accommodation disorder), followed by vascular toxicity (pallor, respiratory (apnea, bradypnea, tachypnea, yawning, respiratory depression) and finally cardiac (cardiac arrest, myocardial depression) Acidosis exacerbates the toxic effects of local anesthetics.

Symptoms due to Epinephrine:

Symptoms are dose-dependent and progressive in severity in the range of neurological manifestations (restlessness, agitation, near-syncope, syncope), followed by vascular (pallor [local, regional, general]), respiratory (apnea [respiratory arrest], bradypnea, tachypnea, respiratory depression) and finally cardiac (cardiac arrest, myocardial depression).

4.5. Safety data

HEALTH	ENVIRONMENT	PHYSICAL
Not classified as dangerous. Substance or mixture exempt from classification under GHS		

GHS: Global Harmonization System.

See safety data sheet

4.6. Contraindications

- Hypersensitivity to the active ingredients, Lidocaine Hydrochloride and Epinephrine, or to any of the excipients.
- Hypersensitivity to any local anesthetic agent.

Due to Lidocaine Hydrochloride.

- Serious cardiac conduction disorders (eg severe bradycardia, second and third degree AV block);
- Acute intermittent porphyria;
- Epileptic patient with insufficient control.

Due to Epinephrine:

- Uncontrolled/severe hypertension
- Severe ischemic heart disease
- Persistent/refractory tachyarrhythmia
- Thyrotoxicosis
- Pheochromocytoma.

4.7. Warnings

Patients with cardiovascular disorders:

- Peripheral vascular disease
- Arrhythmias, especially of ventricular origin
- Heart failure
- Hypotension.

The product should be administered with caution in patients with heart failure as they may be less able to compensate for changes due to atrioventricular canal prolongation.

Patients with epileptic disease:

Due to his seizures, all local anesthetics should be used with great caution.

Patients with liver disease:

The lowest dose that produces effective anesthesia should be used.

Patients with kidney disease:

The lowest dose that produces effective anesthesia should be used.

Patients with coagulopathies:

The increased risk of bleeding after accidental puncture of blood vessels and during maxillofacial surgery should be considered. INR monitoring should be used in patients taking anticoagulants.

Patients with uncontrolled diabetes:

This product should be used with caution due to the hyperglycemic effect of Epinephrine.

Patients susceptible to acute angle-closure glaucoma:

This product should be used with caution due to the presence of Epinephrine.

Elderly patients:

The lowest dose that produces effective anesthesia should be used in patients over 70 years of age.

4.8. Cautions

Risk associated with accidental intravascular injection:

Accidental intravascular injection (e.g. inadvertent intravenous injection) can cause serious adverse reactions, such as seizures, followed by central nervous system depression or cardiorespiratory depression and coma, progressing to respiratory arrest at term due to rapid elevation Epinephrine or Lidocaine Hydrochloride levels in the systemic circulation.

Therefore, to ensure that the needle does not enter a blood vessel during injection, aspiration should be performed prior to injecting the local anesthetic product. However, the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.

Risk associated with an intraneural injection:

An accidental intraneural injection can cause the drug to travel retrograde along the nerve.

In order to avoid intraneural injection and to avoid nerve block-related nerve injury, the needle should be gently withdrawn if the patient feels a sensation of electric shock during the injection or if the injection is particularly painful. If nerve injury occurs, the neurotoxic effect may be aggravated by the neurotoxic potential of Lidocaine Hydrochloride. In addition, the presence of epinephrine can hinder the perineural blood supply and prevent the local evacuation of Lidocaine Hydrochloride.

Risk of Takotsubo cardiomyopathy or stress-induced cardiomyopathy:

Catecholamine injection-induced stress cardiomyopathy has been reported. Due to the presence of Epinephrine, precautions and monitoring should be increased in the following situations: nervous patients before dental treatment; conditions of use that may contribute to inducing a systemic passage of Epinephrine. Any previous knowledge of this underlying state in patients requiring dental anesthesia should

be taken into account to use a minimum dose of local anesthesia with vasoconstrictor.

4.9. Fertility, pregnancy and lactation.

Pregnancy

No effects are anticipated during pregnancy, as systemic exposure to Lidocaine Hydrochloride and Epinephrine is negligible. This product can be used during pregnancy.

In animal studies, effects on reproductive toxicity have been detected with epinephrine at doses higher than those used clinically.

Lactation

Lidocaine Hydrochloride and its metabolites are excreted in human milk, but at therapeutic doses, no effects on newborns and nursing infants are anticipated. This product can be used during lactation.

Fertility

Some animal studies have shown a decrease in female fertility with epinephrine at doses much higher than those used clinically.

4.10. Side effects

Adverse reactions after administration are similar to those seen with other amide local anesthetics combined with vasoconstrictors. These adverse reactions are generally dose-related and may result from elevated plasma levels caused by overdose, rapid absorption, or inadvertent intravascular injection. They may also derive from hypersensitivity, idiosyncrasy, or reduced tolerance on the part of the specific patient.

Nervous system disorders, cardiac disorders and vascular disorders are the most frequently occurring adverse reactions.

Serious adverse reactions are generally systemic. The presence of epinephrine increases the safety profile of the product due to its sympathomimetic effects.

MedDRA CLASSIFICATION BY ORGANS AND SYSTEMS	FREQUENCY	SIDE EFFECTS
Infections and infestations	Very rare	Oral abscess Alveolar osteitis
	Not known	Gingivitis
Immune system disorders	Rare	Hypersensitivity Anaphylactic / anaphylactoid reactions

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Psychiatric disorders	Rare	State of confusion, disorientation Logorrhea
	Very rare	Euphoric mood Anxiety / nervousness / agitation / restlessness
Nervous system disorders	Frequent	Peripheral neuropathy[3]: Neuralgia (neuropathic pain) hypothesia / numbness Dysesthesia, which includes Dysgeusia (eg, metallic taste, taste disorder) [3] Ageusia [3] Headache, Dizziness (loss of balance) Shaking
	Rare	Deep CNS depression: Loss of consciousness Eat Convulsion4 (including tonic clonic seizure) Presyncope, syncope, speech disorder (eg dysarthria) Balance disorder (imbalance syndrome) Drowsiness nystagmus Horner's syndrome 3rd Nerve Palsy (Oculomotor Palsy)
	Very rare	Paresthesia (ie, burning sensation, skin tingling, tingling without apparent physical causes)
Eye disorders [5]	Rare	Ptosis of the eyelids, exophthalmos Diplopia (paralysis of the oculomotor muscles) Amaurosis mydriasis miosis visual impairment Blurry vision Adjustment disorders
Ear and labyrinth disorders	Rare	Vertigo
	Very rare	Tinnitus / Hyperacusis
Heart disorders	Frequent	Palpitations Tachycardia

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	Very rare	Behavior disorders, atrioventricular block) Bradyarrhythmia, Bradycardia Myocardial depression Heart attack Tachyarrhythmia (including ventricular Extrasystoles and ventricular fibrillation)[6] Angina pectoris
Vascular disorders	Frequent	Hypotension (with possible circulatory collapse) Hypertension Paleness (local, regional, general)
	Very rare	Vasodilation Vasoconstriction Hot flushes
Respiratory, thoracic and mediastinal disorders	Frequent	Dyspnoea
	Rare	Bronchospasm / Asthma [2]
	Not known	Respiratory depression Apnea (respiratory arrest) Hypoxia 4 (including cerebral) Hypoventilation Hyperventilation Tachypnea Bradypnea Hypercapnia [4] Yawning Dysphonia (hoarseness[1]) Wheezing
Gastrointestinal disorders	Frequent	Oral (and perioral) hypoaesthesia [3] Oral (and perioral) dysesthesia
	Infrequent	Nausea Vomiting
	Very rare	Oral paraesthesia (and perioral structures) Inflammation of the lips, gums, tongue [8]
	Not known	Gingival/oral mucosal exfoliation (desquamation) / ulceration / dental necrosis [7] Dysphagia [1] Stomatitis, glossitis Diarrhea
Skin and subcutaneous tissue disorders	Infrequent	Rash Pruritus

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	Rare	Angioedema [1] (edema of face/tongue/lip/throat/larynx/periorbital edema) Urticaria
	Very rare	Hyperhidrosis Facial swelling
Musculoskeletal and connective tissue disorders	Infrequent	Myalgia Arthralgia
	Very rare	Muscle contracture, musculoskeletal stiffness Lockjaw
General disorders and administration site conditions	Very rare	Pain Injection site pain Tiredness, asthenia (weakness) Feeling cold, feeling hot, feeling abnormal
	Not known	Chills (shaking) Discomfort Swelling at the injection site Discomfort Pyrexia
Traumatic injuries, intoxications and complications of the intervention	Frequent	Painful procedure (pain after the intervention) Contusion

[1]Angioedema includes edema of the face/tongue/lips/throat/larynx/periorbital. Laryngopharyngeal edema may characteristically occur in conjunction with hoarseness or dysphagia.

[2] Bronchospasm (bronchoconstriction) may characteristically occur with dyspnea.

[3]These neural pathologies can occur with the various symptoms of abnormal sensations (ie paresthesia, hypoesthesia, dysesthesia, etc.) of the lips, tongue, and oral tissues.

[4]Hypoxia and hypercapnia are secondary to respiratory depression or seizures and prolonged muscle exertion

[5] These neurally mediated effects are due to the presence of local anesthetic/ vasoconstrictor at excessive concentrations regionally or in the systemic circulation.

[6]This occurs especially in patients with underlying heart disease or those who are taking certain drugs.

[7]This is due to the excessive local effect of the vasoconstrictor.

[8]This is caused by accidental biting or chewing of the lips or tongue during anesthesia.

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5. QUALITY ASSUREMENT

The product Lidocaine 2% with Epinephrine 1:80,000 is manufactured under the strictest technical and quality controls, its production process is carried out in special manufacturing areas that have environmental, microbiological, operational controls, it is carried out by personnel previously qualified and trained for this type of process. The supplies used in this are previously verified and approved in accordance with the requirements of current pharmacopoeias, this process includes control of packaging materials, raw materials and supplies which are acquired by qualified suppliers.

Product quality characteristics are described below:

PARAMETER	ESPECIFICATION	REFERENCE
Physico-chemical		
Description	Transparent liquid, colorless	USP
Color and transparency	The sample solution does not show a pinkish color or precipitates. The absorbance of the sample solution does not exceed the absorbance of the standard solution	USP
Particulate		
Visible	Each Cartridge must be practically free of visible particles	USP
Sub-visible	The preparation complies with the test if the average number of particles present in the units tested does not exceed 3000 particles equal to or greater than 10 µm per container and does not exceed 300 particles equal to or greater than 25 µm per container.	USP
Delivery volume	The volume is not less than the nominal volume in the case of containers examined individually or, in the case of containers with a nominal volume of 2 mL or less, is not less than the sum of the nominal volumes of the containers taken collectively.	USP
pH	3,3 – 5,5	USP
Instrumental		
Identification		
Lidocaine Hydrochloride	The Lidocaine retention times of the Sample solution correspond to those of the Standard solution, as obtained in the Lidocaine Hydrochloride Assay.	USP

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	The IR spectrum of the preparation obtained from the test sample exhibits maxima only at the same wavelengths as the standard solution.	USP
Epinephrine	The retention times of Epinephrine of the Sample solution correspond to those of the Standard solution, as obtained in the Epinephrine Assay.	USP
Assay		
Lidocaine Hydrochloride	95%-105%	USP
Epinephrine	90%-110%	USP
Antimicrobial Preservative		
Sodium Benzoate	80%-120%	USP
Microbiological		
Mesophiles	No growth of microorganisms	USP
Fungi and Yeast	No growth of microorganisms	USP
Bacterial endotoxins	≤0.7 EU USP / mg of Lidocaine HCl equivalent to 14 EU /mL of injectable solution	USP

6. INSTRUCTIONS

6.1. Preparation and administration.

The cartridges must not be placed in solutions made with anti-corrosion tablets or solutions of quaternary ammonium salts such as benzalkonium chloride. Certain metallic ions, such as mercury, zinc and copper, are contained by disinfectant solutions and these also cause inflammation after anesthesia, therefore, the Cartridges should not be immersed in these solutions. For chemical disinfection of the Cartridge surface, 91% isopropyl alcohol or 70% ethyl alcohol without denaturants is recommended; solutions containing heavy metals are not recommended.

The product should not be used if the solution is colored (pinkish or brownish) or if it contains a precipitate. The anesthetic Lidocaine Hydrochloride 2% with Epinephrine 1:80,000 must not be subjected to a sterilization process by autoclaving, due to thermal decomposition of Epinephrine (thermolabile). Any remaining portion of the Cartridge should be discarded.

This product should only be used by, or under the supervision of, a physician or dentist who is adequately trained and familiar with the diagnosis and treatment of systemic toxicity. The patient's state of consciousness should be monitored after each injection of local anesthesia.

When using Lidocaine Hydrochloride 2% with Epinephrine 1:80,000 for regional anesthetic infiltration or blockade, the injection should always be given slowly and with prior aspiration.

To avoid the risk of infection (eg, transmission of hepatitis), the syringe and needles used to prepare the solution must always be new and sterile. Disposal of unused medication and all materials that have come into contact with it will be done in accordance with local regulations.

6.2. Treatment in case of overdose.

Prior to the administration of regional anesthesia with local anesthetics, adequate resuscitation equipment and drugs must be ensured so that any respiratory or cardiovascular emergency can be treated immediately.

Depending on the severity of overdose symptoms, the physician or dentist should implement protocols that anticipate the need to protect the airway and provide assisted ventilation. The patient's state of consciousness should be monitored after each injection of local anesthesia.

If signs of acute systemic toxicity appear, injection of the local anesthetic should be stopped immediately. If necessary, place the patient in a supine position.

CNS symptoms (seizures, CNS depression) should be treated immediately with appropriate airway/respiratory support and administration of anticonvulsant drugs.

Optimal oxygenation and ventilation, along with circulatory support and treatment of acidosis, can prevent cardiac arrest.

If cardiovascular depression (hypotension, bradycardia) occurs, appropriate treatment with intravenous fluids, vasopressors, or inotropic agents should be considered. Children should be given doses according to their age and weight.

In the event of cardiac arrest, cardiopulmonary resuscitation should be performed immediately.

7. COMMERCIAL PRESENTATIONS

7.1. Nature of primary packaging.

- Type I borosilicate glass cartridge with aluminum clip and Chlorobutyl liner and natural rubber plunger.
- Type I borosilicate glass cartridge with aluminum clip and Chlorobutyl liner and with Bromobutyl plunger

7.2. Nature of secondary packaging.

- Blister of PET material sealed with propalcote paper in a cardboard box
- Polypropylene plastic box
- Metallic container.

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7.3. Approved Presentations.

- Blister box for 80 cartridges of 1.8 mL.
- Blister box for 20 cartridges of 1.8 mL.
- Blister box for 10 cartridges of 1.8 mL.
- Plastic box for 50 cartridges of 1.8 mL.
- Metal container for 40 cartridges of 1.8 mL.
- Metal container for 50 cartridges of 1.8 mL.

7.4. Health certificate

INVIMA 2015M-0004237*

* According to the number of renewals, the registration includes the designation -R. (For example: R1 for the first renewal, R2 for the second and successively)

8. STORAGE CONDITIONS.

8.1. Storage precautions.

Keep out of reach of children. Do not administer if the solution is not clear, contains particles or sediment in the solution.

The injectable product Lidocaine Hydrochloride 2% with Epinephrine 1:80,000 must be stored in a place protected from sunlight, heat or intense light sources. Store at a temperature below 30 °C. Do not freeze.

8.2. Period of validity.

Shelf life of 2 years from the date of manufacture.

8.3. Incompatibilities

Do not store together with alcohols or acrylic monomers.