SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product
Lidocaine Hydrochloride Injection BP 2% w/v.

2. Qualitative and quantitative composition
Each mL contains:
Lidocaine Hydrochloride BP 20 mg
Sodium Chloride BP 6 mg
Methylparaben BP (as preservative) 1 mg
Water for Injections BP q.s

3. Pharmaceutical form
Clear and colorless solution

4. Clinical particulars
4.1 Therapeutic indications
Lidocaine Injection is used as a local anaesthetic.

4.2 Posology and method of administration
For Normal healthy adults, the individual maximum recommended dose of lidocaine hydrochloride without epinephrine should not exceed 4.5 mg.kg (2 mg/lb) of body weight and in general it is recommended that the maximum total dose does not exceed 300 mg.

The maximum recommended dose per 90 minute of lidocaine hydrochloride for paracervical block in obstetrical and nonobstetrical patients is 200 mg total. One half of the total dose is usually administered to each side. Inject slowly, five minutes between sides.

RECOMMENDED DOSAGES OF LIDOCAINE HYDROCHLORIDE INJECTION

Procedure	Concentration (%)	Volume (ml)	Total Dose(mg)
Infilteration Percutaneous Perpheral Nerve Blocks e.g.	0.5 or 1	1 to 60	5 to 300
Brachial	1.5	15 to 20	225 to 300
Dental	2	1 to 5	20 to 100
Intercostal	1	3	30
Paravertebral	1	3 to 5	30 to 50
Pudendal (Each side)	1	10	100
Paracervical Obstetrical Analgesia	1	10	100
Sympathetic Nerve Blocks			
Cervical (Stellate Gangilion)	1	5	50
Lumber	1	5 to 10	50 to 100

The above suggested concentrations and volumes serve only as a guide. Other volumes and concentrations may be used provided the total maximum recommended dose is not exceeded.

Children
It is difficult to recommend a maximum dose of any drug for children, since this varies as a function of age and weight. For children over three years of age who have a normal lean body mass and normal body development, the maximum dose is determined by the child's age and weight. For example, in a child of five years weighing 50 lbs., the dose of lidocaine hydrochloride should not exceed 75 to 100 mg (1.5 to 2 mg/lb).
In order to guard against systemic toxicity, the lowest effective concentration and lowest effective dose should be used at all times. In some cases it will be necessary to dilute available concentrations with 0.9% Sodium Chloride Injection in order to obtain the required final concentration.

Lidocaine Hydrochloride Injection has been found to be chemically stable for 24 hours after dilution in 5% dextrose in water. However, as with all intravenous admixtures, dilution of the solution should be made just prior to its administration.
When administering lidocaine hydrochloride (or any potent medication) by continuous intravenous infusion, it is advisable to use a precision volume control I.V. set.
Pediatric: Controlled clinical studies in the pediatric population to establish dosing schedules have not been conducted. The American Heart Association's Standards and Guidelines recommends a bolus dose of 1 mg/kg, and an infusion rate of between 20-50 µg/kg/min for prolonged therapy. When drug clearance is reduced, as in patients with shock, congestive heart failure or cardiac arrest, the infusion rate should not exceed 20 µg/kg/min.
NOTE: Regarding Prolonged Infusions: There are data that indicate the half-life may be 3 hours or longer following infusions of greater than 24 hours in duration. Do not use if solution is discolored or cloudy.

4.3 Contraindications
- Known hypersensitivity to lidocaine or other anaesthetics of the amide type
- Known hypersensitivity to hydroxybenzoates
- Complete heart block
- Hypovolaemia

4.4 Special warnings and precautions for use
As with other local anaesthetics, lidocaine should be used with caution in patients with epilepsy, cardiac conduction disturbances, (see also section 4.3 Contraindications) congestive cardiac failure, bradycardia, severe shock, impaired respiratory function or impaired renal function with a creatinine clearance of less than 10mL/minute. Lidocaine is metabolised in the liver and it should be used with caution in patients with impaired hepatic function. Lidocaine should not be used in cases of acute porphyrias.

Patients with myasthenia gravis are particularly susceptible to the effects of local anaesthetics.
Facilities for resuscitation should be available when administering local anaesthetics.
The effect of local anaesthetics may be reduced if the injection is made into an inflamed or infected area.

Certain local anaesthetic procedures may be associated with serious adverse reactions, regardless of the local anaesthetic drug used.
- Retrobulbar injections may rarely reach the cranial subarachnoid space, causing serious/severe reactions, including cardiovascular collapse, apnoea, convulsions and temporary blindness
- Retro- and peribulbar injections of local anaesthetics carry a low risk of persistent ocular motor dysfunction. The primary causes include trauma and/or local toxic effects on muscles and/or nerves.

The severity of such tissue reactions is related to the degree of trauma, the concentration of the local anaesthetic and the duration of exposure of the tissue to the local anaesthetic. For this reason, as with all local anaesthetics, the lowest effective concentration and dose of local anaesthetic should be used.

Hameln Lidocaine Injection is not recommended for use in neonates. The optimum serum concentration of lidocaine required to avoid toxicity, such as convulsions and cardiac arrhythmias, in this age group is not known.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of Lidocaine on other medicinal products

Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics (e.g. anti-arrhythmics, such as mexiletine), since the systemic toxic effects are additive. Specific interaction studies with lidocaine and class III anti-arrhythmic drugs (e.g. amiodarone) have not been performed, but caution is advised.
There may be an increased risk of enhanced and prolonged neuromuscular blockade in patients treated concurrently with muscle relaxants (e.g. suxamethonium).

Effects of other medicinal products on Lidocaine

There may be an increased risk of ventricular arrhythmia in patients treated concurrently with antipsychotics which prolong or may prolong the QT interval (e.g. pimozide, sertindole, olanzapine, quetiapine, zotepine), or $5HT_3$ antagonists (e.g. tropisetron, dolasetron).
Concomitant use of quinupristin/dalfopristin should be avoided.
Hypokalaemia produced by acetazolamide, loop diuretics and thiazides antagonises the effect of lidocaine.

The clearance of lidocaine may be reduced by beta-adrenoceptor blocking agents (e.g. propranolol) and by cimetidine, requiring a reduction in the dosage of lidocaine. Increase in serum levels of lidocaine may also occur with anti-viral agents (e.g. amprenavir, atazanavir, darunavir, lopinavir).

Cardiovascular collapse has been reported following the use of bupivacaine in patients on treatment with verapamil and timolol; lidocaine is closely related to bupivacaine.
While adrenaline (epinephrine) when used in conjunction with lidocaine might decrease vascular absorption, it greatly increases the danger of ventricular tachycardia and fibrillation if accidentally injected intravenously.

4.6 Fertility, pregnancy and lactation

Pregnancy

Although animal studies have revealed no evidence of harm to the foetus, lidocaine crosses the placenta and should not be administered during early pregnancy unless the benefits are considered to outweigh the risks.
Lidocaine given by local perineal infiltration prior to delivery crosses rapidly into the foetal circulation. Elevated lidocaine levels may persist in the newborn for at least 48 hours after delivery. Foetal bradycardia or neonatal bradycardia, hypotonia or respiratory depression may occur.

Lactation

Small amounts of lidocaine are secreted into breast milk and the possibility of an allergic reaction in the infant, albeit remote, should be borne in mind when using lidocaine in nursing mothers.

4.7 Effects on ability to drive and use machines
Where outpatient anaesthesia affects areas of the body involved in driving or operating machinery, patients should be advised to avoid these activities until normal function is fully restored.

4.8 Undesirable effects
In common with other local anaesthetics, adverse reactions to lidocaine are rare and are usually the result of raised plasma concentrations due to accidental intravascular injection, excessive dosage or rapid absorption from highly vascular areas, or may result from a hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. Systemic toxicity mainly involves the central nervous system and/or the cardiovascular system (see also 4.9 Overdose).
Solutions of lidocaine which contain preservatives are not suitable for spinal, epidural or caudal anaesthesia. Adverse effects reported following unpreserved lidocaine solutions administered by this route include hypotension and isolated cases of bradycardia and cardiac arrest.

Immune system disorders
Hypersensitivity reactions (allergic or anaphylactoid reactions, anaphylactic shock) – see also Skin & subcutaneous tissue disorders)
Skin testing for allergy to Lidocaine is not considered to be reliable.

Nervous & Psychiatric disorders
Neurological signs of systemic toxicity include dizziness or light-headedness, nervousness, tremor, circumoral paraesthesia, tongue numbness, drowsiness, convulsions, coma.
Nervous system reactions may be excitatory and or depressant. Signs of CNS stimulation may be brief, or may not occur at all, so that the first signs of toxicity may be confusion and drowsiness, followed by coma and respiratory failure.

Neurological complications of spinal anaesthesia include transient neurological symptoms such as pain of the lower back, buttock and legs. These symptoms usually develop within twenty-four hours of anaesthesia and resolve within a few days. Isolated cases of arachnoiditis or cauda equina syndrome, with persistent paraesthesia, bowel and urinary dysfunction, or lower limb paralysis have been reported following spinal anaesthesia with lidocaine and other similar agents. The majority of cases have been associated with hyperbaric concentrations of lidocaine or prolonged spinal infusion.

Eye disorders
Blurred vision, diplopia and transient amaurosis may be signs of lidocaine toxicity.
Bilateral amaurosis may also be a consequence of accidental injection of the optic nerve sheath during ocular procedures. Orbital inflammation and diplopia have been reported following retro- or peribulbar anaesthesia (see section 4.4 Special warnings and precautions for use)

Ear and labyrinth disorders
Tinnitus, hyperacusis

Cardiac and vascular disorders
Cardiovascular reactions are depressant and may manifest as hypotension, bradycardia, myocardial depression, cardiac arrhythmias and possibly cardiac arrest or circulatory collapse.

Respiratory, thoracic or mediastinal disorders
Dyspnoea, bronchospasm, respiratory depression, respiratory arrest

Gastrointestinal disorders
Nausea, vomiting

Skin & subcutaneous tissue disorders
Rash, urticaria, oedema (including angioedema, face oedema)

Blood and the lymphatic system disorders
Methaemoglobinaemia.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows
continued monitoring of the benefit/risk balance of the medicinal product. Health care providers are asked to
report any suspected adverse reactions to the marketing authorisation holder, or, if available, vi a the national reporting system (see details below).

Paper based reporting: TMDA yellow card
Online reporting: https://sqrt.tmda.go.tz/
*USSD reporting: send a simple short text message to report any suspected Adverse Drug Reaction by dialing *152*00# and follow the instructions*

4.9 Overdose
Symptoms of acute systemic toxicity
Central nervous system toxicity presents with symptoms of increasing severity. Patients may present initially with circumoral paraesthesia, numbness of the tongue, light-headedness, hyperacusis and tinnitus. Visual disturbance and muscular tremors or muscle twitching are more serious and precede the onset of generalised convulsions. These signs must not be mistaken for neurotic behaviour. Unconsciousness and grand mal convulsions may follow, which may last from a few seconds to several minutes. Hypoxia and hypercapnia occur rapidly following convulsions due to increased muscular activity, together with the interference with normal respiration and loss of the airway. In severe cases, apnoea may occur. Acidosis increases the toxic effects of local anaesthetics.

Effects on the cardiovascular system may be seen in severe cases. Hypotension, bradycardia, arrhythmia and cardiac arrest may occur as a result of high systemic concentrations, with potentially fatal outcome.

Recovery occurs as a consequence of redistribution of the local anaesthetic drug from the central nervous system, and metabolism and may be rapid unless large amounts of the drug have been injected.

Treatment of acute toxicity
If signs of acute systemic toxicity appear, injection of the anaesthetic should be stopped immediately.

Treatment will be required if convulsions and CNS depression occurs. The objectives of treatment are to maintain oxygenation, stop the convulsions and support the circulation.

A patent airway should be established and oxygen should be administered, together with assisted ventilation (mask and bag) if necessary. The circulation should be maintained with infusions of plasma or intravenous fluids. Where further supportive treatment of circulatory depression is required, use of a vasopressor agent may be considered although this involves a risk of central nervous system excitation.

If the convulsions do not stop spontaneously in 15-20 seconds, they may be controlled by the intravenous administration of diazepam or thiopentone sodium, bearing in mind that anti-convulsant drugs may also depress respiration and the circulation. Prolonged convulsions may jeopardise the patient's ventilation and oxygenation and early endotracheal intubation should be considered. If cardiac arrest should occur, standard cardiopulmonary resuscitation procedures should be instituted. Continual optimal oxygenation and ventilation and circulatory support as well as treatment of acidosis are of vital importance.

Dialysis is of negligible value in the treatment of acute overdosage with lidocaine.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetic, ATC code: N01BB02.

Lidocaine is a local anaesthetic of the amide group. It is used to provide local anaesthesia at various sites in the body and it acts by inhibiting the ionic refluxes required for the initiation and conduction of impulses, thereby stabilising the neuronal membrane. In addition to blocking conduction in nerve axons in the peripheral nervous system, lidocaine has important effects on the central nervous system and cardiovascular system. After absorption, lidocaine may cause stimulation of the CNS followed by depression. In the cardiovascular system, it acts primarily on the myocardium where it may produce decreases in electrical excitability, conduction rate and force of contraction.

5.2 Pharmacokinetic properties

Lidocaine is absorbed from injection sites including muscle and its rate of absorption is determined by factors such as the site of administration and the tissue vascularity. Except for intravascular administration, the highest blood levels occur following intercostal nerve block and the lowest after subcutaneous administration. Lidocaine is bound to plasma proteins, including alpha-1-acid-glycoprotein. The drug crosses the blood-brain and placental barriers.

Lidocaine is metabolised in the liver and about 90 % of a given dose undergoes N-dealkylation to form monoethylglycinexylidide and glycinexylidide, both of which may contribute to the therapeutic and toxic effects of lidocaine. Further metabolism occurs and metabolites are excreted in the urine with less than 10 % of unchanged lidocaine. The elimination half-life of lidocaine following an intravenous bolus injection is one to two hours, but this may be prolonged in patients with hepatic dysfunction.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Chloride BP 6 mg
Methylparaben BP (as preservative) 1 mg
Water for Injections BP q.s

6.2 Incompatibilities

Lidocaine causes precipitation of amphotericin, methohexitone sodium and sulfadiazine sodium in glucose injection. It is recommended that admixtures of lidocaine and glyceryl trinitrate should be avoided.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30ºC in a dry place. Protect from light

6.5 Nature and contents of container

30 ml plain glass vial (USP Type-1) such single vial is packed in a box

6.6 Special precautions for disposal and other handling

Use as directed by a physician.

7. Marketing authorisation holder

Swiss Parenterals Ltd
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Nr. Prahaladnagar Garden, Anandnagar Road, Satellite,
Ahmedabad-380015, Gujarat,
INDIA

8. Marketing authorisation number(s)

TAN 20 HM 0111

9. Date of first authorisation/renewal of the authorisation

July 09, 2020

10. Date of revision of the text

October 12, 2023