1. Product Information

1. Prescribing Information (Summary of Product Characteristics)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Lidocaine 2% and Adrenaline (1:2,00,000) Injection BP 30 ml

1.1 PRODUCT NAME

Lidocaine 2% and Adrenaline (1:2,00,000) Injection BP 30 ml

1.1 STRENGTH

2%

1.2 PHARMACEUTICAL FORM

Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 QUALITATIVE DECLARATION:

Lidocaine 2% and Adrenaline (1:200,000) Injection BP, 30 ml

2.2 QUANTITATIVE DECLARATION

Each ml Contains:
Lidocaine Hydrochloride BP……..20.0 mg
Adrenaline Acid Tartrate BP
Equivalent to Adrenaline …..……0.005 mg
Methyl paraben BP……...1 mg
(As preservative)
Water for injections BP ……... ….q. s. to 1 ml.

3. PHARMACEUTICAL FORM

Solution for Injection

A clear & colourless solution free from visible particles and fibers.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Lidocaine 2% with Adrenaline is indicated for regional Anesthesia in adults and children above 12 years of age.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Adults and children above 12 years of age

The dosage is adjusted according to the response of the patient and the site of administration. The lowest concentration and smallest dose producing the required effect should be given. The maximum single dose of Xylocaine when given with adrenaline is 500 mg.

The following table is a guide for the more commonly used techniques in the average adult. The figures reflect the expected average dose range needed. Standard textbooks should be consulted for factors affecting specific block techniques and for individual patient requirements.

The clinician's experience and knowledge of the patient's physical status are of importance in calculating the required dose. Elderly or debilitated patients require smaller doses, commensurate with age and physical status.

Type of block	% Conc.	Each dose		Indication
		ml	mg	
Field Block (e.g. minor nerve blocks and infiltration)				
Infiltration	1	up to 15	up to 150	Surgical operations
Intercostals (per nerve)	1	2-5 Max. 15 ml	20-50 Max. 150 mg	Surgical operations Postoperative pain and fractured ribs
Pudendal	1	10	100	Instrumental delivery
Major Nerve Block				
Paracervical (each side)	1	10	100	Surgical operations and dilatation of cervix Obstetric pain relief
Sciatic	2	15	300	Surgical operations

For local anaesthesia only.

Preservative containing solutions should not be used intracisternally, epidurally, intrathecally or by any route giving access to the cerebrospinal fluid, or intra- or retro-bulbary. The volume to be injected in a single dose should not exceed 15 ml, unless otherwise justified.

In general, surgical anaesthesia requires the use of higher concentrations and doses. When a less intense block is required, the use of a lower concentration is indicated. The volume of drug used will affect the extent and spread of anaesthesia.

Care should be taken to prevent acute toxic reactions by avoiding intravascular injection. Careful aspiration before and during the injection is recommended. An accidental intravascular injection may be recognised by a temporary increase in heart rate. The main dose, should be injected slowly, at a rate of 100-200 mg/min, or in incremental doses, while keeping in constant verbal contact with the patient. If toxic symptoms occur, the injection should be stopped immediately.

4.3 CONTRAINDICATIONS

Hypersensitivity to the active substance, to any of the excipients or to local anaesthetics of the amide type.

Hypersensitivity to methyl and/or propyl parahydroxybenzoate (methyl-/propyl paraben), or to their metabolite para amino benzoic acid (PABA). Formulations of lidocaine containing parabens should be avoided in patients allergic to ester local anaesthetics or their metabolite PABA.

The use of a vasoconstrictor is contraindicated for anaesthesia of fingers, toes, tip of nose, ears and penis.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Regional anaesthetic procedures should always be performed in a properly equipped and staffed area. Equipment and drugs necessary for monitoring and emergency resuscitation should be immediately available. When performing major blocks, or using large doses, an IV cannula should be inserted before the local anesthetic is injected. Clinicians should have received adequate and appropriate training in the procedure to be performed and should be familiar with the diagnosis and treatment of side effects, systemic toxicity or other complications.

Lidocaine with Adrenaline should not be given intravenously.

The effect of local anaesthetics may be reduced if an injection is made into an inflamed or infected area.

Attempts should be made to Optimise the patient's condition before major blocks.
Although regional anaesthesia is frequently the optimal anaesthetic technique, some patients require special attention in order to reduce the risk of dangerous side effects:
- Patients with epilepsy.
- Patients with impaired respiratory function.
- Older people and patients in poor general condition.
- Patients with partial or complete heart conduction block - due to the fact that local anaesthetics may depress myocardial conduction.
- Patients with advanced liver disease or severe renal dysfunction.
- Patients treated with anti-arrhythmic drugs class III (e.g. amiodarone) should be under close surveillance and ECG monitoring considered, since cardiac effects may be additive.
- Patients with acute porphyria. Lidocaine solution for injection is probably porphyrinogenic and should only be prescribed to patients with acute porphyria on strong or urgent indications. Appropriate precautions should be taken for all porphyric patients.
Certain local anaesthetic procedures may be associated with serious adverse reactions, regardless of the local anaesthetic drug used, e.g.:
- Injections in the head and neck regions may be made inadvertently into an artery, causing cerebral symptoms even at low doses.
- Paracervical block can sometimes cause foetal bradycardia/tachycardia, and careful monitoring of the foetal heart rate is necessary.
- There have been post-marketing reports of chondrolysis in patients receiving post-operative intra-articular continuous infusion of local anaesthetics. The majority of reported cases of chondrolysis have involved the shoulder joint. Due to multiple contributing factors and inconsistency in the scientific literature regarding mechanism of action, causality has not been established. Intra-articular continuous infusion is not an approved indication for Lidocaine.
Solutions containing adrenaline should be used with caution in patients with hypertension, cardiac disease, cerebrovascular insufficiency hyperthyroidism, advanced diabetes and any other pathological condition that may be aggravated by the effects of adrenaline.
Lidocaine with adrenaline contains sodium metabisulphite, which may cause allergic reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence

of sulphite sensitivity in the general population is unknown and probably low. Sulphite sensitivity is seen more frequently in asthmatic than non-asthmatic people.

For local anaesthesia only.

Preservative containing solutions should not be used intracisternally, epidurally, intrathecally or by any route giving access to the cerebrospinal fluid, or intra- or retro-bulbary. The volume to be injected in a single dose should not exceed 15 ml, unless otherwise justified.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g. certain anti-arrhythmics, such as mexilitine, since the systemic toxic effects are additive. Specific interaction studies with lidocaine and anti-arrhythmic drugs class III (e.g. amiodarone) have not been performed, but caution is advised.

Drugs that reduce the clearance of lidocaine (e.g. cimetidine or betablockers) may cause potentially toxic plasma concentrations when lidocaine is given in repeated high doses over a long time period. Such interactions should be of no clinical importance following short term treatment with lidocaine at recommended doses.

Solutions containing adrenaline should be used cautiously in patients taking tricyclic antidepressants, monoamine oxidase inhibitors or receiving potent general anaesthetic agents since severe, prolonged hypertension may be the result. In addition, the concurrent use of adrenaline-containing solutions and oxytocic drugs of the ergot type may cause severe, persistent hypertension and possibly cerebrovascular and cardiac accidents. Phenothiazines and butyrophenones may oppose the vasoconstrictor effects of adrenaline giving rise to hypotensive responses and tachycardia.

Solutions containing adrenaline should be used with caution in patients undergoing general anaesthesia with inhalation agents, such as halothane and enflurane, due to the risk of serious cardiac arrhythmias.

Non-cardioselective betablockers such as propranolol enhance the pressor effects of adrenaline, which may lead to severe hypertension and bradycardia.

4.6 PREGNANCY AND LACTATION

Pregnancy

Although there is no evidence from animal studies of harm to the foetus, as with all drugs, Lidocaine should not be given during early pregnancy unless the benefits are considered to outweigh the risks.
The addition of adrenaline may potentially decrease uterine blood flow and contractility, especially after inadvertent injection into maternal blood vessels.
Foetal adverse effects due to local anaesthetics, such as foetal bradycardia, seem to be most apparent in paracervical block anaesthesia. Such effects may be due to high concentrations of anaesthetic reaching the foetus.

Breast-feeding
Lidocaine may enter the mother's milk, but in such small amounts that there is generally no risk of this affecting the neonate. It is not known whether adrenaline enters breast milk or not, but it is unlikely to affect the breast-fed child.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Besides the direct anaesthetic affect, local anaesthetics may have a very mild effect on mental function and co-ordination, even in the absence of overt CNS toxicity, and may temporarily impair locomotion and alertness.

4.8 UNDESIRABLE EFFECTS

In common with other local anaesthetics, adverse reactions to Lidocaine with Adrenaline are rare and are usually the result of excessively high blood concentrations due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally to hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. In such circumstances systemic effects occur involving the central nervous system and/or the cardiovascular system.
The adverse reaction profile for Lidocaine with adrenaline is similar to those of other amide local anaesthetics. Adverse reactions caused by the drug per se are difficult to distinguish from the physiological effects of the nerve block (e.g. decrease in blood pressure, bradycardia), events caused directly (e.g. nerve trauma) or indirectly by the needle puncture.

Tabulated list of Adverse Reactions

Frequencies are defined as very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to<1/1,000), very rare (<1/10,000) or not known (cannot be estimated from the available data).

The following table gives a list of the frequencies of undesirable effects:

System Organ Class	Frequency Classification	Adverse Drug Reaction
Immune system disorders	Rare	Allergic reactions, anaphylactic reaction
Nervous system disorders	Common	Paraesthesia, dizziness
	Uncommon	Signs and symptoms of CNS toxicity (convulsions, numbness of tongue and paraesthesia circumoral, tinnitus, tremor, dysarthria, hyperacusis, visual disturbances, CNS depression)
	Rare	Neuropathy, peripheral nerve injury, arachnoiditis
Eye disorders	Rare	Diplopia
Cardiac disorders	Common	Bradycardia
	Rare	Cardiac arrest, cardiac arrhythmias
Vascular disorders	Common	Hypotension, hypertension
Respiratory, thoracic and mediastinal disorders	Rare	Respiratory depression
Gastrointestinal disorders	Common	Nausea, vomiting

4.9 OVERDOSE

Accidental intravascular injections of local anaesthetics may cause immediate (within seconds to a few minutes) systemic toxic reactions. In the event of overdose, systemic toxicity appears later (15–60 minutes after injection) due to the slower increase in local anaesthetic blood concentration.

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMICS PROPERTIES

Pharmacotherapeutic group (ATC code): N01B B52

Lidocaine is a local anaesthetic of the amide type. At high doses lidocaine has a quinidine like action on the myocardium i.e. cardiac depressant. All local anaesthetics stimulate the CNS and may produce anxiety, restlessness and tremors.

5.2 PHARMACOKINETIC PROPERTIES

Lidocaine is readily absorbed from the gastro-intestinal tract, from mucous membranes and through damaged skin. It is rapidly absorbed from injection sites including muscle.

Elimination half-life is 2 hours.

Lidocaine undergoes first pass metabolism in the liver.

Less than 10% of a dose is excreted unchanged via the kidneys.

The speed of onset and duration of action of lidocaine are increased by the addition of a vasoconstrictor and absorption into the site of injection is reduced.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENT(S)

Sodium Chloride BP
Disodium EDTA BP
Sodium Metabisulphite BP
Methyl Paraben BP
Citric Acid Anhydrous BP
Water for Injections BP

6.2 INCOMPATIBILITIES

Lidocaine caused precipitation of Amphotericin, Methohexitone Sodium and Sulfadiazine Sodium in Glucose Injection. It is recommended that admixtures of Lidocaine & Glyceryl trinitrate should be avoided.

6.3 SHELF-LIFE

24 Months

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not above 30°C in dry place. Protect from light.

KEEP OUT OF REACH OF CHILDREN

Use within 30 days of first opening.

6.5 NATURE AND CONTENTS OF CONTAINER

30 ml plain glass vial (USP Type-I) packed in a carton along with Insert.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SWISS PARENTERALS LTD.

808, 809, & 810 Kerala Industrial Estate, G.I.D.C,

Nr, Bavla, Dist. Ahmedabad-382 220.

Gujarat, India.

8. MARKETING AUTHORISATION NUMBER

TAN 21 HM 0229

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

3rd June, 2021

10. DATE OF REVISION / APPROVAL OF THE TEXT

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11. LEGAL CATEGORY

Prescription Only Medicine.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.