

# **NEW ZEALAND DATA SHEET**

## **1. PRODUCT NAME**

Xylocaine 1% Solution for Injection  
Xylocaine 2% Solution for Injection  
Xylocaine 1% with Adrenaline 1:100,000 Solution for Injection  
Xylocaine 1% with Adrenaline 1:200,000 Solution for Injection  
Xylocaine 2% with Adrenaline 1:200,000 Solution for Injection

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Xylocaine 1%: Each mL of solution for injection contains 10mg of lidocaine hydrochloride.  
Xylocaine 2%: Each mL of solution for injection contains 20mg of lidocaine hydrochloride.  
Xylocaine 1% with Adrenaline 1:100,000: Each mL of solution for injection contains 10mg of lidocaine hydrochloride and 10micrograms of adrenaline (epinephrine) as acid tartrate.  
Xylocaine 1% with Adrenaline 1:200,000: Each mL of solution for injection contains 10mg of lidocaine hydrochloride and 5micrograms of adrenaline (epinephrine) as acid tartrate.  
Xylocaine 2% with Adrenaline 1:200,000: Each mL of solution for injection contains 20mg of lidocaine hydrochloride and 5micrograms of adrenaline (epinephrine) as acid tartrate.

(Note: Lidocaine is another name for lignocaine. Lidocaine is used in this document. Epinephrine is another name for adrenaline. Adrenaline is mostly used in this document.)

For full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

XYLOCAINE solution for injection is a sterile, isotonic aqueous solution. The pH of the solution is 5.0-7.0. The ampoules are free from preservatives and are intended for single use only.

XYLOCAINE with adrenaline solution for injection is a sterile, isotonic aqueous solution. It contains sodium metabisulphite as an antioxidant. The pH of the solution is 3.3-5.0.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

XYLOCAINE solutions are indicated for the production of local or regional anaesthesia by the following techniques:

- local infiltration
- minor or major nerve blocks
- epidural block
- arthroscopy
- intravenous regional anaesthesia

## 4.2 Dose and method of administration

### ADULTS AND CHILDREN ABOVE 12 YEARS

The following table is a guide to dosage 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. The lowest dose required for adequate anaesthesia should be used (see section 4.4). Individual variations in onset and duration occur. *The duration may be prolonged with the adrenaline-containing solutions.*

*NB. Risk of systemic effects of adrenaline with large volumes of adrenaline-containing solutions should be considered.*

**Table 1 Dosage Recommendations**

| Type of block   | Conc.<br>mg/ml | Dose<br>without/with adrenaline |         | Onset<br>(min) | Duration of effect (h)   |                    |
|---|----------------|---------------------------------|---------|----------------|--------------------------|--------------------|
|   |                | ml                              | mg      |                | Without<br>adrenaline    | With<br>adrenaline |
| <b>SURGICAL ANAESTHESIA</b>                                   |                |                                 |         |                |                          |                    |
| Lumbar Epidural Administration <sup>1)</sup>                  | 20             | 15-25                           | 300-500 | 15-20          | 1.5-2                    | 2-3                |
| Thoracic Epidural Administration <sup>1)</sup>                | 15             | 10-15                           | 150-225 | 10-20          | 1-1.5                    | 1.5-2              |
|   | 20             | 10-15                           | 200-300 | 10-20          | 1.5-2                    | 2-3                |
| Caudal Epidural Block <sup>1)</sup>                           | 10             | 20-30                           | 200-300 | 15-30          | 1-1.5                    | 1-2                |
|   | 20             | 15-25                           | 300-500 | 15-30          | 1.5-2                    | 2-3                |
| IV Regional (Bier's block)                                    |                |                                 |         |                |                          |                    |
| a. Upper limb <sup>2)</sup>                                   | 5              | 40                              | 200     | 10-15          | Until tourniquet release | NR                 |
| b. Lower limb <sup>2)</sup>                                   |                |                                 |         |                | - " -                    |                    |
| i) thigh tourniquet   | 5              | 60                              | 300     | 10-15          | - " -                    | NR                 |
| ii) calf tourniquet   | 5              | 40                              | 200     | 10-15          |                          | NR                 |
| Intra-articular block <sup>3)</sup>                           | 5              | ≤60                             | ≤300    | 5-10           | 30-60 min after washout  |                    |
|   | 10             | ≤40                             | ≤400    | 5-10           |                          |                    |
| <b>FIELD BLOCK (eg. minor nerve blocks and infiltration)</b>  |                |                                 |         |                |                          |                    |
| Infiltration  | 5              | ≤80                             | ≤400    | 1-2            | 1.5-2                    | 2-3                |
|   | 10             | ≤40                             | ≤400    | 1-2            | 2-3                      | 3-4                |
| Digital block   | 10             | 1-5                             | 10-50   | 2-5            | 1.5-2                    | NR                 |
| Intercostals (per nerve)                                      | 10             | 2-5                             | 20-50   | 3-5            | 1-2                      | 3-4                |
|   | 15             | 2-4                             | 30-60   | 3-5            | 2-3                      | 4-5                |
| [Maximal number of nerves blocked at same time should be ≤ 8] |                |                                 |         |                |                          |                    |

| Type of block  | Conc.<br>mg/ml | Dose<br>without/with adrenaline |         | Onset<br>(min) | Duration of effect (h) |                    |
|--|----------------|---------------------------------|---------|----------------|------------------------|--------------------|
|  |                | ml                              | mg      |                | Without<br>adrenaline  | With<br>adrenaline |
| Retrobulbar  | 20             | 4                               | 80      | 1.5-2          | 1.5-2                  | 2-4                |
| Peribulbar   | 10             | 10-15                           | 100-150 | 1.5-2          | 1.5-2                  | 2-4                |
| Pudendal<br>(each side)  | 10             | 10                              | 100     | 5-10           | 1.5-2                  | 2-3                |
| <b>MAJOR NERVE BLOCK</b>   |                |                                 |         |                |                        |                    |
| Paracervical<br>(each side)  | 10             | 10                              | 100     | 3-5            | 1-1.5                  | 2-2.5              |
| Brachial plexus:   |                |                                 |         |                |                        |                    |
| Axillary   | 10             | 40-50                           | 400-500 | 15-30          | 1.5-2                  | 3-4                |
|  | 15             | 30-50                           | 450-600 | 15-30          | 1.5-3                  | 3-5                |
| Supraclavicular,<br>interscalene and<br>subclavian<br>perivascular | 10             | 30-40                           | 300-400 | 15-30          | 1.5-2                  | 3-4                |
|  | 15             | 20-30                           | 300-450 | 15-30          | 1.5-3                  | 3-5                |
| Sciatic  | 15             | 15-20                           | 225-300 | 15-30          | 2-3                    | 3-4                |
|  | 20             | 15-20                           | 300-400 | 15-30          | 2-3                    | 3-4                |
| 3 in 1<br>(Femoral,<br>obturator and<br>lateral cutaneous)         | 10             | 30-40                           | 300-400 | 15-30          | 1.5-2                  | 2-4                |
|  | 15             | 30                              | 450     | 15-30          | 2-3                    | 3-5                |

## Remarks:

- 1) Dose includes test dose
- 2) Do not deflate tourniquet within 20 min of injection
- 3) There have been post marketing reports of chondrolysis in patients receiving post-operative intra-articular continuous infusion of local anaesthetics. XYLOCAINE is not approved for this indication (Also see section 4.4).

≤ = up to

NR = not recommended

In general, surgical anaesthesia (e.g. epidural administration) requires the use of the 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.

In order to avoid intravascular injection, aspiration should be repeated prior to and during administration of the main dose, which should be injected slowly or in incremental doses, at a rate of 100-200 mg/min, while closely observing the patient's vital functions and maintaining verbal contact. *When an epidural dose is to be injected, a preceding test dose of 3-5 mL short-acting local anaesthetic, containing adrenaline is recommended.* An inadvertent intravascular injection may be recognized by a temporary increase in heart rate and an accidental intrathecal injection by signs of a spinal block. If toxic symptoms occur, the injection should be stopped immediately.

## PAEDIATRIC PATIENTS 1 TO 12 YEARS OF AGE

**Table 2 Dosage Recommendations in Children**

|                 | Conc.   | Volume             |                  | Dose               |                 | Onset | Duration (h)       |                 |
|-----------------|---------|--------------------|------------------|--------------------|-----------------|-------|--------------------|-----------------|
|                 | (mg/mL) | without adrenaline | with adrenaline  | without adrenaline | with adrenaline | (min) | Without adrenaline | with adrenaline |
| Caudal epidural | 10      | 0.5                | <i>up to 0.7</i> | 5                  | <i>up to 7</i>  | 10-15 | 1-1.5              | <i>1.5-2</i>    |

Consider both age and weight for calculation of dosages

The doses in Table 2 should be regarded as guidelines for use in paediatrics. Individual variations occur. In children with a high body weight a gradual reduction of the dosage is often necessary and should be based on the ideal body weight. Standard textbooks should be consulted for factors affecting specific block techniques and for individual patient requirements.

### 4.3 Contraindications

Known hypersensitivity to local anaesthetics of the amide type, or to any of the excipients.

- Known hypersensitivity to sodium metabisulphite in solutions containing adrenaline.

### 4.4 Special warnings and precautions for use

Regional or local anaesthetic procedures, except those of the most trivial nature, should always be performed in a properly equipped and staffed area, with the equipment and medicines necessary for monitoring and emergency resuscitation immediately available. When performing major blocks or using large doses, an IV cannula should be inserted before the local anaesthetic 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. (See section 4.9)

Although regional anaesthesia is frequently the optimal anaesthetic technique, some patients require special attention in order to reduce the risk of dangerous side effects:

- The elderly and patients in poor general condition.
- Patients with partial or complete heart block - due to the fact that local anaesthetics may depress myocardial conduction.
- Patients with advanced liver disease or severe renal dysfunction.
- Patients being 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 (see section 4.5).
- Patients with acute porphyria. Lidocaine 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.

- There have been post-marketing reports of chondrolysis in patients receiving postoperative 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 XYLOCAINE.

Certain local anaesthetic procedures may be associated with serious adverse reactions, regardless of the local anaesthetic, for example:

- Central nerve blocks may cause cardiovascular depression, especially in the presence of hypovolaemia and therefore epidural anaesthesia should be used with caution in patients with impaired cardiovascular function.
- Retrobulbar injections may very occasionally reach the cranial subarachnoid space, causing temporary blindness, cardiovascular collapse, apnoea, convulsions etc.
- Retro- and peribulbar injections of local anaesthetics carry a low risk of persistent ocular muscle 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. Vasoconstrictors may aggravate tissue reactions and should be used only when indicated.

- 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 fetal bradycardia/tachycardia, and careful monitoring of the fetal heart rate is necessary.

Epidural anaesthesia may lead to hypotension and bradycardia. This risk of such effects can be reduced, e.g. by injecting a vasopressor. Hypotension should be treated promptly with a sympathomimetic intravenously, repeated as necessary.

*Solutions containing adrenaline should be used with caution in patients with severe or untreated hypertension, poorly controlled hyperthyroidism, ischemic heart disease, heart block, cerebrovascular insufficiency, advanced diabetes and any other pathological condition that might be aggravated by the effects of adrenaline. These solutions should also be used cautiously and in carefully restricted quantities in areas of the body supplied by end arteries, such as digits, or otherwise having a compromised blood supply (see section 4.5).*

*XYLOCAINE with adrenaline solutions contain sodium metabisulphite, a sulphite that may cause allergic-type 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 in nonasthmatic people.*

Local anaesthetic solutions containing antimicrobial preservatives, should not be used for intrathecal anaesthesia.

#### 4.5 Interaction with other medicines 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 and tocainide, 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 should be advised (see section 4.4).

Drugs that reduce the clearance of lidocaine (e.g. cimetidine or beta-blockers) 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 generally be avoided or used with care in patients receiving tricyclic antidepressants since severe, prolonged hypertension may be the result.*

*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. Neuroleptics such as phenothiazines 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 Fertility, pregnancy and lactation

##### Pregnancy

It is reasonable to assume that a large number of pregnant women and women of child-bearing age have been given lidocaine. No specific disturbances to the reproductive process have so far been reported, e.g. no increased incidence of malformations.

Fetal adverse effects due to local anaesthetics, such as fetal bradycardia, seem to be most apparent in paracervical block anaesthesia. Such effects may be due to high concentrations of anaesthetic reaching the fetus.

*The addition of adrenaline may potentially decrease uterine blood flow and contractility, especially after inadvertent injection into maternal blood vessels.*

##### Lactation

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 effect, local anaesthetics may have a very mild effect on mental function and coordination even in the absence of overt CNS toxicity and may temporarily impair locomotion and alertness.

## 4.8 Undesirable effects

### GENERAL

The adverse reaction profile of XYLOCAINE 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 (e.g. epidural abscess) by the needle puncture.

### TABLE OF ADVERSE DRUG REACTIONS

|                              |   |
|------------------------------|---|
| Common<br>(>1/100<1/10)      | Vascular disorders: hypotension, hypertension<br><br>Gastrointestinal disorders: nausea, vomiting<br><br>Nervous system disorders: paraesthesia, dizziness<br><br>Cardiac disorders: bradycardia  |
| Uncommon<br>(>1/1,000<1/100) | Nervous system disorders: signs and symptoms of CNS toxicity (convulsions, paraesthesia circumoral, numbness of the tongue, hyperacusis, visual disturbances, tremor, tinnitus, dysarthria, CNS depression)   |
| Rare<br>(<1/1,000)           | Cardiac disorders: cardiac arrest, cardiac arrhythmias<br>Immune system disorders: allergic reactions, anaphylactic reaction/shock.<br><br>Respiratory disorders: respiratory depression<br><br>Nervous system disorders: neuropathy, peripheral nerve injury, arachnoiditis<br><br>Eye disorders: diplopia |

### ACUTE SYSTEMIC TOXICITY

Systemic toxic reactions primarily involve the central nervous system (CNS) and the cardiovascular system (CVS). Such reactions are caused by high blood concentrations of a local anaesthetic, which may appear due to (accidental) intravascular injection, overdose or exceptionally rapid absorption from highly vascularised areas (see section 4.9). CNS reactions are similar for all amide local anaesthetics, while cardiac reactions are more dependent on the drug, both quantitatively and qualitatively. Signs of toxicity in the central nervous system generally precede cardiovascular toxic effects, unless the patient is receiving a general anaesthetic or is heavily sedated with drugs such as benzodiazepine or barbiturate.

**Central nervous system** toxicity is a graded response with symptoms and signs of escalating severity. The first symptoms are usually, circumoral paraesthesia, numbness of the tongue, light-headedness, hyperacusis, tinnitus and visual disturbances. Dysarthria, muscular twitching or tremors are more serious and precede the onset of generalized convulsions. These signs must not be mistaken for a neurotic behaviour. Unconsciousness and grand mal convulsions may follow which may last from a few seconds to several

minutes. Hypoxia and hypercarbia occur rapidly following convulsions due to the increased muscular activity, together with the interference with respiration and possible loss of functional airways. In severe cases apnoea may occur. Acidosis, hyperkalaemia, hypocalcaemia and hypoxia increase and extend the toxic effects of local anaesthetics.

Recovery is due to redistribution of the local anaesthetic drug from the central nervous system and subsequent metabolism and excretion. Recovery may be rapid unless large amounts of the drug have been injected.

**Cardiovascular system toxicity** may be seen in severe cases and is generally preceded by signs of toxicity in the central nervous system. In patients under heavy sedation or receiving a general anaesthetic, prodromal CNS symptoms may be absent. Hypotension, bradycardia, arrhythmia and even cardiac arrest may occur as a result of high systemic concentrations of local anaesthetics, but in rare cases cardiac arrest has occurred without prodromal CNS effects.

In children, early signs of local anaesthetic toxicity may be difficult to detect in cases where the block is given during general anaesthesia.

## TREATMENT OF ACUTE TOXICITY

If signs of acute systemic toxicity appear, injection of the local anaesthetic should be stopped immediately and CNS symptoms (convulsion, CNS depression) must be promptly treated with appropriate airway/respiratory support and the administration of anticonvulsant drugs.

If circulatory arrest should occur, immediate cardiopulmonary resuscitation should be instituted. Optimal oxygenation and ventilation and circulatory support as well as treatment of acidosis are of vital importance.

If cardiovascular depression occurs (hypotension, bradycardia), appropriate treatment with intravenous fluids, vasopressor, chronotropic and or inotropic agents should be considered. Children should be given doses commensurate with age and weight.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting/>

## OVERDOSAGE

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Lidocaine hydrochloride (XYLOCAINE) is a local anaesthetic of the amide type. It has a rapid onset and a medium duration of action. The 2% solution will last 1½-2 h when given



epidurally, and up to 5 hours with peripheral nerve blocks. When used in concentrations of 1%, there is less effect on motor nerve fibres and the duration of action is shorter.

Onset and the duration of the local anaesthetic effect of lidocaine depends on the dose and the site of administration. *The presence of adrenaline may prolong the duration of action for infiltration and peripheral nerve blocks but has less marked effect on epidural blocks.*

Lidocaine, like other local anaesthetics, causes a reversible blockade of impulse propagation along nerve fibres by preventing the inward movement of sodium ions through the cell membrane of the nerve fibres. The sodium channels of the nerve membrane are considered a receptor for local anaesthetic molecules.

Local anaesthetics may have similar effects on other excitable membranes e.g. brain and myocardium. If excessive amounts of medicine reach the systemic circulation, symptoms and signs of toxicity may appear, emanating mainly from the central nervous and cardiovascular systems.

Central nervous system toxicity (see section 4.9) usually precedes the cardiovascular effects, as central nervous system toxicity occurs at lower plasma concentrations. Direct effects of local anaesthetics on the heart include slow conduction, negative inotropism and eventually cardiac arrest.

Indirect cardiovascular effects (hypotension, bradycardia) may occur after epidural administration depending on the extent of the concomitant sympathetic block.

## 5.2 Pharmacokinetic properties

Lidocaine has a pKa of 7.9, an oil/water partition coefficient of 2.9, and is 65% protein-bound (mainly to alpha-1-acid glycoprotein) in plasma.

*The plasma concentration of lidocaine depends upon the dose, the route of administration and the vascularity of the injection site. Absorption is slowed considerably by the addition of adrenaline, although it also depends on the site of injection. Peak plasma concentrations are reduced by 50% following subcutaneous injection, by 30% following epidural injection and by 20% following intercostal block if adrenaline 5 µg/ml is added.*

Lidocaine shows complete and biphasic absorption from the epidural space with half-lives of the two phases in the order of 9.3 min and 82 min respectively. The slow absorption is the rate-limiting factor in the elimination of lidocaine, which explains why the apparent terminal half-life is longer after epidural administration. Absorption of lidocaine from the subarachnoid space is monophasic with an absorption half-life of 71 min.

Lidocaine has a total plasma clearance of 0.95 L/min, a volume of distribution at steady state of 91 L, a terminal half-life of 1.6 h and an estimated hepatic extraction ratio of 0.65. The clearance of lidocaine is almost entirely due to liver metabolism, and depends both on liver blood flow and the activity of metabolising enzymes.

The terminal half-life in neonates (3.2 h) is approximately twice that of adults, whereas clearance is similar (10.2 mL/min kg).

Lidocaine readily crosses the placenta and equilibrium with regard to the unbound concentration is rapidly reached. The degree of plasma protein binding in the fetus is less than in the mother, which results in lower total plasma concentrations in the fetus.

Lidocaine is excreted in breast milk, but in such small quantities that there is no risk of affecting the child with therapeutic doses.

The main metabolites formed from lidocaine are monoethylglycine xylidide (MEGX), glycinexylidide (GX), 2,6-xylidine and 4-hydroxy-2,6-xylidine. The N-dealkylation to MEGX, is considered to be mediated by both CYP1A2 and CYP3A4. The metabolite 2,6-xylidine is converted to 4-hydroxy-2,6-xylidine by CYP2A6 and the latter is the major urinary metabolite in man. Only 3% of lidocaine is excreted unchanged. About 70% appears in the urine as 4-hydroxy-2,6-xylidine.

MEGX has a convulsant activity similar to that of lidocaine and a somewhat longer half-life. GX lacks convulsant activity and has a half-life of about 10 h.

### 5.3 Preclinical safety data

In animal studies, the signs and symptoms of toxicity noted after high doses of lidocaine are the results of the effects of the central nervous system and cardiovascular systems. No drug related adverse effects were seen in reproduction toxicity studies, neither did lidocaine show a mutagenic potential in either *in vitro* or *in vivo* mutagenicity tests. Cancer studies have not been performed with lidocaine, due to the area and duration of therapeutic use for this medicine.

Genotoxicity tests with lidocaine showed no evidence of mutagenic potential. A metabolite of lidocaine, 2,6-xylidine, showed weak evidence of activity in some genotoxicity tests. The metabolite, 2,6-xylidine has been shown to have carcinogenicity potential in preclinical toxicological studies evaluating chronic exposure. Risk assessments comparing the calculated maximum human exposure from intermittent use of lidocaine, with the exposure used in preclinical studies, indicate a wide margin of safety for clinical use.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

#### XYLOCAINE

- Sodium chloride
- Sodium hydroxide
- Hydrochloric acid
- Water for injections

#### XYLOCAINE with Adrenaline

- Sodium chloride
- Sodium hydroxide
- Hydrochloric acid
- Water for injections
- Sodium metabisulphite

All presentations are free from preservative and are intended for single use only.

### 6.2 Incompatibilities

The solubility of lidocaine is limited at pH >6.5. This must be taken into consideration when alkaline solutions, i.e. carbonates, are added since precipitation might occur. *In the case of adrenaline-containing solutions, mixing with alkaline solutions may cause rapid degradation of adrenaline.*

### 6.3 Shelf life

#### Glass Ampoules

*XYLOCAINE with adrenaline* 18 months

#### Plastic Ampoules (Polyamp®)

XYLOCAINE  
 2 mL: 18 months  
 5 mL: 36 months  
 20 mL: 24 months

#### Single Dose Vials

*XYLOCAINE with adrenaline* 18 months

### 6.4 Special precautions for storage

#### Glass Ampoules

*XYLOCAINE with adrenaline* Store at or below 25°C

#### Plastic Ampoules (Polyamp®)

XYLOCAINE  
 2 mL: Store at or below 25°C  
 5 mL: Store at or below 25°C  
 20 mL: Store at or below 30°C

#### Single Dose Vials

*XYLOCAINE with adrenaline* Store at or below 25°C

### 6.5 Nature and contents of container

Vials made of colourless glass with rubber stoppers.

Colourless glass ampoules

Plastic ampoules (Polyamp®)

#### Polyamps

1% 2 mL x 50  
 1% 5 mL x 50  
 1% 20 mL x 5 AstraZeneca Theatre Pack  
 2% 2 mL x 50  
 2% 5 mL x 50  
 2% 20 mL x 5 AstraZeneca Theatre Pack

#### Glass Ampoules

*With adrenaline*

1% with adrenaline 1:100,000 5 mL x 10

#### Single Dose Vials

*With adrenaline*

1% with adrenaline 1:200,000 20 mL x 5 AstraZeneca Theatre Pack

2% with adrenaline 1:200,000 20 mL x 5 AstraZeneca Theatre Pack

## 6.6 Special precautions for disposal and other handling

All solutions should be used immediately after opening of the container. Any remaining solution must be discarded.

Re-sterilisation of Xylocaine is not recommended. NB. Due to the characteristics of the material in the Polyamp system, the plastic ampoules (Polyamp®), these must not be re-sterilized.

*Due to the instability of adrenaline, products containing adrenaline must not be sterilized.*

*Adequate precautions should be taken to avoid prolonged contact between local anaesthetic solutions containing adrenaline (low pH) and metal surfaces (e.g. needles or metal parts of syringes), since dissolved metal ions, particularly copper ions, may cause severe local irritation (swelling, oedema) at the site of injection and accelerate the degradation of adrenaline.*

## 7. MEDICINE SCHEDULE

Prescription Medicine.

## 8. SPONSOR

Pharmacy Retailing (NZ) Limited trading as Healthcare Logistics  
58 Richard Pearse Drive  
Airport Oaks  
Auckland  
New Zealand  
Telephone: (09) 918 5100  
Email: [aspen@aspenpharma.co.nz](mailto:aspen@aspenpharma.co.nz)

## 9. DATE OF FIRST APPROVAL

31 December 1969

## 10. DATE OF REVISION OF THE TEXT

10 August 2023

## SUMMARY TABLE OF CHANGES

| Section changed | Summary of new information   |
|-----------------|--|
| 8.              | Additional company contact details as required by SPC-style format |
| 4.4             | Update of warning regarding hypotension or bradycardia             |
| 6.3             | Shelf life updated for 5mL plastic ampoule                         |
| 2               | Remove (lignocaine) from ingredient name                           |