NEW ZEALAND DATA SHEET

1. PRODUCT NAME
Xylocaine® Viscous solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each mL of Xylocaine Viscous contains lidocaine hydrochloride monohydrate 21.4 mg (equivalent to lidocaine hydrochloride 20 mg).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Xylocaine Viscous solution is a clear to almost clear slightly coloured viscous liquid.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Xylocaine Viscous solution is indicated for the relief of pain and discomfort associated with:

- irritated or inflamed mucous membranes of the mouth, pharynx and upper gastrointestinal tract, e.g. post-tonsillectomy sore throat, dumping syndrome;
- introduction of instruments and catheters into the respiratory and gastrointestinal tract.

4.2 Dose and method of administration
As with any local anaesthetic, reactions and complications are best averted by employing the minimal effective dosage. Debilitated, acutely ill or elderly patients and children should be given doses commensurate with their age and physical condition.

Shake the bottle well before use.

For symptomatic treatment of irritated or inflamed mucous membranes of the mouth and pharynx, the usual adult dose is 15 mL undiluted. For use in the mouth, the solution should be swished around the mouth for approximately 30 seconds and spat out. For use on the pharynx, the solution should be gargled and may be swallowed. This dose should not be administered at intervals of less than three hours.

MAXIMUM DOSAGE

Although the incidence of adverse effects with lidocaine is quite low, caution should be exercised when using large amounts.

Adults: No more than 15 mL (300 mg lidocaine HCl) every 3 hours or 120 mL in a 24 hour period.

Children over 3 years of age: No more than 4 mg/kg (0.2 mL/kg) of bodyweight or 5 mL (100 mg lidocaine HCl), whichever is lower. No more than 4 doses should be given in a 24 hour period. The dose should not be administered at intervals of less than three hours. It is recommended that excess solution is spat out.

Children under 3 years of age: No more than 4 mg/kg (0.2 mL/kg) of bodyweight or 1.25 mL (25 mg lidocaine HCl) whichever is lower, accurately measured and applied only to the affected area with a cotton swab. No more than 4 doses should be given in a 24 hour period. This dose should not be administered at intervals of less than three hours.

At the present time there is not enough documentation to allow recommendations for a more prolonged use of Xylocaine Viscous in children under the age of 3 years.

The solution should not be administered to sooth teething pain in infants and children because of safety concerns.

4.3 Contraindications

Known history of hypersensitivity to lidocaine or other local anaesthetics of the amide type or to other components of the viscous solution.

Hypersensitivity to methyl and/or propyl hyroxybenzoate or to their metabolite para aminobenzoic acid.

4.4 Special warnings and precautions for use

Warning: Excessive dosage, or short intervals between doses, can result in high levels of lidocaine or its metabolites and serious adverse effects. In order to prevent serious adverse effects, patients should be instructed to strictly adhere to the recommended dosage and administration guidelines. The management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs (see OVERDOSAGE).

Patients should not exceed the recommended dose or use Xylocaine Viscous for prolonged periods except on the advice of their physician.

The lowest dose that results in effective anaesthesia should be used to avoid high plasma levels and serious adverse effects. Tolerance to elevated blood levels varies with the status of the patient.

Excessive dosage or short intervals between doses may result in high plasma levels and serious adverse effects. Following too high or repeated doses, including accidental ingestion of viscous lidocaine in infants and children under the age of three years, serious side effects have been reported involving the cardiovascular and central nervous systems including fatal outcomes. Patients should be instructed to adhere strictly to the

recommended dosage. This is especially important in children where the doses vary with weight.

PAEDIATRIC PATIENTS

Post-marketing cases of seizures, cardiopulmonary arrest and death in patients under the age of 3 years have been reported with use of xylocaine viscous when it was not administered in strict adherence to the dosing and administration recommendations. Xylocaine viscous should not be administered to infants and children for teething pain. For other conditions, the use of the product in patients less than 3 years of age should be limited to those situations where safer alternatives are not available or have been tried but failed.

To decrease the risk of serious adverse events with use of xylocaine viscous, instruct caregivers to strictly adhere to the prescribed dose and frequency of administration and store the bottle safely out of reach of children."

Dosage reduction

Debilitated, elderly patients or patients with partial or complete heart block and/or acutely ill patients, and children should be given reduced doses commensurate with their age and physical status.

Excessive absorption

Absorption from wound surfaces and mucous membranes is relatively high, especially in the bronchial tree. Because of the possibility of significant systemic absorption, Xylocaine Viscous should be used with caution in patients with traumatised mucosa and/or sepsis in the region of the proposed application.

In order to prevent serious adverse effects, if the dose or site of administration is likely to result in high blood levels, lidocaine, in common with other local anaesthetics, should be used with caution in patients with epilepsy, impaired cardiac conduction, bradycardia, impaired hepatic function, in severe shock, the elderly, patients in poor general health and patients with severe renal dysfunction.

Patients treated with anti-arrhythmic drugs class III (e.g. amiodarone) should be kept under close surveillance and ECG monitoring considered, since cardiac effects may be additive.

Eating and drinking

The use of topical anaesthetic agents in the oral cavity may interfere with swallowing and thus enhance the danger of aspiration of food or drink. For this reason, food or drink should not be ingested within 60 minutes of using local anaesthetics in the mouth or throat area. Numbness of the tongue or buccal mucosa may increase the danger of biting or heat trauma. Food, chewing gum or hot drinks should not be taken while the mouth or throat area is anaesthetised.

Malignant hyperthermia

Many drugs used during the conduct of anaesthesia are considered potential triggering agents for familial malignant hyperthermia. It has been shown that the use of amide local anaesthetics in malignant hypothermia patients is generally safe, but cases of malignant hyperthermia have been occasionally documented after use.

Endotracheal tube lubrication

When used for endotracheal tube lubrication care should be taken to avoid introduction of the viscous solution into the lumen of the tube. The solution may dry on the inner surface leaving residue which tends to clump with flexion, narrowing the lumen. There have been rare reports in which this residue has caused the lumen to occlude.

Porphyric patients

Xylocaine Viscous is probably porphyrinogenic and should only be used on patients with acute porphyria where there are strong or urgent indications. Appropriate precautions should be taken for all porphyric patients.

Carcinogenic and Mutagenic Potential

Genotoxicity tests with lidocaine are inconclusive. In genotoxicity studies, a metabolite of lidocaine, 2,6-xylidine, showed evidence of activity in some tests but not in other tests. This metabolite has been shown to have carcinogenic potential (nasal and subcutaneous tumours) in preclinical toxicological studies evaluating chronic exposure.

4.5 Interactions with other medicines and other forms of interaction

Antiarrhythmic drugs

Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. antiarrhythmic drugs such as mexiletine, since the 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.

Enzyme inducing drugs

Cimetidine or betablockers have been shown to cause potentially toxic plasma concentrations when lidocaine is given in repeated high doses over a long period of time. Therefore, caution should be taken if lidocaine was administered at higher than recommended doses over extended period of time.

Phenytoin and other antiepileptic drugs such as phenobarbitone, primidone and carbamazepine appear to enhance the metabolism of lidocaine but the significance of this effect is not known. Phenytoin and lidocaine have additive cardiac depressant effects.

4.6 Fertility, pregnancy and lactation

Pregnancy - Category A

Lidocaine crosses the placental barrier and may be taken up by foetal tissues. When used for surface anaesthesia, lidocaine blood levels after normal doses are low so little drug is available for placental transfer.

There are, however, no adequate and well-controlled studies in pregnant women. Reproduction studies have been performed in rats at doses of 500 mg/kg/day and have revealed no evidence of harm to the foetus caused by lidocaine.

It is reasonable to assume that a large number of pregnant women and women of child-bearing age have used lidocaine. No specific disturbances to the reproduction process have so far been reported.

Labour and delivery

Lidocaine is not contraindicated in labour and delivery.

Using in lactation

Lidocaine enters the breast milk, but in such small quantities that there is generally no risk of affecting the child at therapeutic dose levels.

4.7 Effects on ability to drive and use machines

Depending on the dose, local anaesthetics may have a very mild effect on mental function and may temporarily impair locomotion and co-ordination.

4.8 Undesirable effects

Systemic adverse reactions are rare and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy or reduced tolerance on the part of the patient. Such reactions are systemic in nature and involve the central nervous system and/or the cardiovascular system.

Central Nervous System

CNS reactions are excitatory and/or depressant and may be characterised by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness and possibly respiratory arrest. The excitatory reactions may be brief or may not occur at all, in which case the first manifestations of toxicity may be drowsiness, progressing to unconsciousness and respiratory arrest.

Drowsiness following administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a result of rapid absorption.

Cardiovascular

Cardiovascular reactions are usually depressant and may be characterised by hypotension, myocardial depression, bradycardia and possibly cardiac arrest.

Allergic reactions

Allergic reactions may occur as a result of sensitivity either to the local anaesthetic agent or to other ingredients in the formulation. Allergic reactions as a result of sensitivity to lidocaine are rare (<0.1%). The detection of sensitivity by skin testing is of doubtful value.

The extremely rare cases of allergy to local anaesthetic preparations have included bronchospasm, chest pain, dyspnoea, pruritus, rash, rhinitis, increased sweating, urticaria, sleepiness, dizziness, paraesthesia, oedema, and in the most severe instances anaphylactic shock. Several cases of contact dermatitis have been reported with the use of lidocaine.

Reporting of suspected adverse reactions

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 to https://nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

For information on the management of overdose, contact the National Poisons and Centre Ph 0800 POISON (0800 764 766).

Management of Local Anaesthetic Emergencies

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient's state of consciousness after each local anaesthetic administration. At the first sign of change, oxygen should be administered.

Treatment of Overdosage

Should symptoms of systemic toxicity occur, the signs are anticipated to be similar in nature to those following the administration of local anaesthetics by other routes. Local anaesthetic toxicity is manifested by symptoms of nervous system excitation and, in severe cases, central nervous and cardiovascular depression.

Severe neurological symptoms (convulsions, CNS depression) must be treated symptomatically by respiratory support and the administration of anti-convulsive 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.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Lidocaine, the active ingredient of Xylocaine Viscous, stabilises the neuronal membrane and prevents the initiation and conduction of nerve impulses, thereby effecting local anaesthetic action.

The onset of action of Xylocaine Viscous occurs within 3-5 minutes on mucous membranes. Its low surface tension ensures an even film over the surface of the mucous membrane so that the lidocaine comes into intimate contact with the total surface. High viscosity ensures sufficiently prolonged contact with the mucous membrane. It is ineffective when applied to intact skin.

5.2 Pharmacokinetic properties

Lidocaine may be absorbed following topical administration to mucous membranes, its rate of absorption and amount of dose absorbed depending upon concentration and total dose administered, the specific site of application and duration of exposure. In general, the rate of absorption occurs most rapidly after intratracheal administration.

Lidocaine is well absorbed from the gastrointestinal tract, but little intact drug appears in the circulation because of bio transformation in the liver. Lidocaine is metabolised rapidly by the liver, and metabolites and unchanged drug are excreted by the kidney.

Excessive blood levels may cause changes in cardiac output, total peripheral resistance and mean arterial pressure. These changes may be attributable to a direct depressant effect of the anaesthetic agent on various components of the cardiovascular system.

Biotransformation includes oxidative N-dealkylation, ring hydroxylation, cleavage of the amide linkage and conjugation. The pharmacological / toxicological actions of the metabolites are similar to, but not less potent than, those of lidocaine. Approximately 90% of lidocaine is excreted in the form of various metabolites, and less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2,6-dimethylaniline.

The plasma binding of lidocaine is dependent on drug concentration, and the fraction bound decreases with increasing concentration. At concentrations of 1 to 4 µg of free base/mL, 60 to 80% of lidocaine is protein bound. Binding is also dependent on the plasma concentrations of the alpha-1-acid glycoprotein.

Lidocaine crosses the blood-brain and placental barriers, presumably by passive diffusion.

Studies of lidocaine metabolism following intravenous bolus injection have shown that the elimination half-life is usually 1.5 to 2 hours. The half-life may be prolonged 2-fold or more in patients with liver dysfunction. Renal dysfunction does not affect lidocaine kinetics, but may increase the accumulation of metabolites.

Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce overt systemic effects. Objective adverse manifestations become increasingly apparent with increasing venous plasma levels above 6.0 µg free base/mL. In the rhesus monkey arterial blood levels of 18 to 21 µg/mL have been shown to be the threshold for convulsive activity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate, propyl hydroxybenzoate, sodium hydroxide, saccharin sodium, cherry flavour, carmellose sodium, citric acid anhydrous and purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

200 mL bottle

6.6 Special precautions for disposal and other handling

Not applicable

7. MEDICINE SCHEDULE

Pharmacy Only Medicine

8. SPONSOR

Pharmacy Retailing (NZ) Limited t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks
Auckland
New Zealand

9. DATE OF FIRST APPROVAL

22/5/1997

10. DATE OF REVISION OF THE TEXT

22 August 2024

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All sections	Update to the SPC-style format

4.4	Paediatric patients
All sections	Replace “lignocaine” with “lidocaine”