SCHEDULING STATUS: **S4**

PROPRIETARY NAME: **XYLOTOX E80-A**

(AND DOSAGE FORM) **(INJECTION)**

COMPOSITION:

Each 1 ml contains:

Lidocaine HCl 20 mg (2 % m/v)

Adrenaline 12,5 µg (1:80 000)

Antioxidant: Sodium metabisulphite

Sugar free

List of excipients: Citric acid monohydrate, hydrochloric acid, silicone, sodium hydroxide, nitrogen, sodium chloride and water for injection.

PHARMACOLOGICAL CLASSIFICATION:

A.4 Local anaesthetics

PHARMACOLOGICAL ACTION:

Lidocaine HCl with adrenaline produces local anaesthesia. It has prolonged duration and reduced systemic absorption due to the vasoconstrictor action of adrenaline.

INDICATIONS:

XYLOTOX E80-A is a local anaesthetic solution with a vasoconstrictor. It is used for dental infiltration anaesthesia where a vasoconstrictor is indicated. For all dental nerve block techniques.

CONTRAINDICATIONS:

Hypersensitivity to local anaesthetics of the amide type i.e. lidocaine hydrochloride. It should not be given to patients with thyrotoxicosis and cardiac disease, particularly those with arrhythmia, hypertension, narrow angle glaucoma and patients on tricyclic antidepressants.

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Local anaesthetics should not be given to patients with myasthenia gravis.

WARNINGS:

Minimal effective doses should not be exceeded and careful observation of certain fundamental precautions is essential. It is also important to be in constant readiness to cope with reactions due to overdosage, individual patient idiosyncrasy, faulty technique and/or inadvertent intravascular injection. **XYLOTOX E80-A** may not be used in children under the age of 2 years.

INTERACTIONS:

Sympathomimetics may increase blood pressure and therefore special care is advisable in patients receiving antihypertensive therapy. Interactions of sympathomimetic agents with alpha- and beta-blocking medicines may be complex.

PREGNANCY AND LACTATION:

Pregnancy:

Safety in pregnancy has not been established.

Lactation:

Lidocaine is distributed into breast milk, therefore it is advisable not to breastfeed while clinical action is still present at the jaw.

DOSAGE AND DIRECTIONS FOR USE:

Infiltration: 1 ml

Nerve block: 1,5 ml to 2,0 ml

Extensive surgery: 3,0 ml to 5,0 ml

The maximum adult dose of lidocaine hydrochloride given with adrenaline is 500 mg (25 ml). In children the maximum dose is considerably less and should be calculated in relation to the body mass. Do not exceed the recommended dose.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Side effects:

The type of toxic reactions are unpredictable and depend on dosage, route of administration and state of the patient. The reactions are primarily of two types and typified by stimulation or depression of the cerebral cortex and medulla respectively.

XYLOTOX E80-A may cause methaemoglobinaemia.

Side effects occur rapidly and with little warning:

Nervous system disorders:

The following side effects have been reported and frequencies are rare:

Dizziness and convulsions.

The following side effects have been reported and frequencies are unknown:

Nervousness and tremors.

Eye disorders:

The following side effect has been reported and the frequency is unknown:

Blurred vision.

Cardiac disorders:

The following side effect has been reported and the frequency is unknown:

Cardiac arrest.

Vascular disorders:

The following side effect has been reported and the frequency is unknown:

Cardiovascular collapse.

Respiratory, thoracic and mediastinal disorders:

The following side effect has been reported and the frequency is rare:

Respiratory arrest.

Symptoms occur rapidly and with little warning.

Gastrointestinal disorders:

The following side effect has been reported and the frequency is rare:

Nausea.

Special precautions:

XYLOTOX E80-A should be given cautiously to patients with epilepsy, impaired cardiac conduction, or with liver damage.

Epinephrine (Adrenaline) should be used with caution in patients receiving MAO inhibitors (or within 10 days of their discontinuation).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage may produce the symptoms listed above, followed by convulsions, bradycardia, hypotension, respiratory arrest, circulatory collapse and coma.

Adequate resuscitation must be available whenever local anaesthesia is administered. Although clinical tolerance is remarkably good, overdosage or accidental intravenous injection may give rise to toxic reactions. These are best avoided by aspiration before making an injection in order to avoid accidental intravascular injection.

Treatment is symptomatic and supportive. Convulsions may be controlled with a short-acting barbiturate.

IDENTIFICATION:

XYLOTOX E80-A dental cartridges are clear glass cartridges containing a clear, colourless solution, free of particulate matter. The glass cartridge is labelled with the product name.

PRESENTATION:

Tins of 100 x 1,8 ml dental cartridges.

10 x 10 blisters of 1,8 ml dental cartridges packed into a cardboard carton.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

Date of approval: 11 October 2013

REGISTRATION NUMBER:

South Africa: P/4/170

Namibia: NS2 90/4/00185

Botswana: B9300875 S2

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

11 October 2013