SCHEDULING STATUS: **S4**

PROPRIETARY NAME AND DOSAGE FORM:

XYLOTOX S.E. PLAIN solution for injection

COMPOSITION:

Each 1,0 ml contains:

Lidocaine hydrochloride 20 mg (2 % *m/v*)

Preservative: Methyl hydroxybenzoate 0,1 % *m/v*

Sugar free

List of excipients: Sodium Chloride, Sodium Hydroxide and Water for injection.

PHARMACOLOGICAL CLASSIFICATION:

A.4 Local anaesthetics

PHARMACOLOGICAL ACTION:

XYLOTOX S.E. PLAIN contains Lidocaine, a local anaesthetic of low toxicity which possesses considerable advantages over older local anaesthetics in regard to depth, duration and rapidity of onset of full anaesthesia. These advantages are combined with a very low incidence of local and general side reactions.

INDICATIONS:

Local anaesthesia or dental extractions and operations.

CONTRAINDICATIONS:

Hypersensitivity to Lidocaine.

Date of approval: 01 June 2020

WARNINGS AND SPECIAL PRECAUTIONS:

Therapeutic doses are non-toxic, but local anaesthetics should be used with caution in patients with impaired cardiac conduction or with liver damage. Care must be exercised to avoid intravenous injection, since, in such case, the rapid absorption is likely to cause systemic toxic symptoms, such as hypotension, pallor, arrhythmias, sweating, nausea, vomiting and muscular twitching.

XYLOTOX S.E. PLAIN may not be used in children under the age of 2 years.

DOSAGE AND DIRECTIONS FOR USE:

As with any local anaesthetic, dosage will depend on the anaesthetic requirements as determined by the nature, magnitude, duration and locality of the operation in view. When used with a vasoconstrictor, one 1,8 ml cartridge is usually sufficient for most procedures. However, extended procedures may require 3 ml to 10 ml. It has been estimated that the maximum permissible adult dose of Lidocaine 2 % solutions plus a vasoconstrictor is 25 ml. When used without a vasoconstrictor, the more rapid absorption necessitates 50 % higher dosage levels than those above to produce equivalent anaesthesia, but the more rapid absorption increases toxicity so that the maximum permissible adult dose is 12 ml. Do not exceed the recommended dose.

SIDE EFFECTS:

Allergy to Lidocaine is rare, but allergic and anaphylactic reactions have been reported. Cross-allergy between anaesthetics of the Lidocaine group has also been reported. **XYLOTOX S.E. PLAIN** may cause methaemoglobinaemia.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosing will cause the same symptoms as intravenous injection, such as hypotension, pallor, arrhythmias, sweating, nausea, vomiting and muscular twitching. In severe poisoning these symptoms are likely to be followed by convulsions and respiratory and circulatory collapse. Treat by intravenous injections of a short acting barbiturate and apply artificial respiration if needed.

Date of approval: 01 June 2020

IDENTIFICATION:

XYLOTOX S.E. PLAIN dental cartridges are clear, glass cartridges containing a clear, colourless solution. The glass cartridge is labelled with the product name.

PRESENTATION:

Cans 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.

REGISTRATION NUMBER:

G 2799 (Act 101/1965)

Namibia: NS2 03 1002192 (Act No. 13 of 2003)

Botswana: B9300870 S2

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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01 June 2020

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