SCHEDULING STATUS: **S4**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM: XYLOTOX E80-A (INJECTION)

Read this entire leaflet before you start using XYLOTOX E80-A.

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist. XYLOTOX E80-A has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT XYLOTOX E80-A CONTAINS:

Each 1 ml of **XYLOTOX E80-A** contains lidocaine 20 mg and adrenaline 12,5 µg.

The other ingredients are: Citric acid monohydrate, hydrochloric acid, silicone, sodium hydroxide, nitrogen, sodium chloride, sodium metabisulphite and water for injection.

Sugar free

WHAT XYLOTOX E80-A IS USED FOR:

XYLOTOX E80-A is an injection which produces local anaesthesia (loss of sensation or pain).

XYLOTOX E80-A is used for dental infiltration and all dental nerve block techniques.

BEFORE YOU USE XYLOTOX E80-A:

Do not use XYLOTOX E80-A:

- If you are hypersensitive (allergic) to lidocaine or adrenaline or any of the other ingredients of **XYLOTOX E80-A**.
- If you have an overactive thyroid.
- If you have heart disease, especially an irregular heartbeat.
- If you have narrow angle glaucoma (raised pressure in the eye).
- If you are taking tricyclic antidepressants.

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Take special care with XYLOTOX E80-A and tell your doctor if:

- You have myasthenia gravis (a disorder causing muscle weakness).
- You suffer from epilepsy (fits).
- You have impaired cardiac conduction (the process that causes the heart muscles to expand and contract rhythmically).
- You suffer from liver damage.
- You are taking medicine for high blood pressure.
- If you are, or have been (within the previous 10 days) been taking monoamine oxidase inhibitors (MAOI's), which is a medicine for depression.

XYLOTOX E80-A may not be used in children under the age of 2 years.

Pregnancy and Breast-feeding:

If you are pregnant or breast-feeding your baby while using XYLOTOX E80-A, please consult your doctor, pharmacist or other healthcare professional for advice.

Pregnancy:

Safety in pregnancy has not been established.

Breastfeeding:

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

Taking other medicines with XYLOTOX E80-A:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of XYLOTOX E80-A with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

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There may be interactions between adrenaline and alpha blocking agents (e.g. medicines used for high blood pressure) and beta-blocking agents (e.g. medicines used for heart disease and high blood pressure).

HOW XYLOTOX E80-A SHOULD BE GIVEN TO YOU:

XYLOTOX E80-A should only be administered by a Healthcare Professional.

POSSIBLE SIDE EFFECTS:

XYLOTOX E80-A can have side effects.

Not all side effects reported for **XYLOTOX E80-A** are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may be experienced while using **XYLOTOX E80-A.**

If you experience any of the following side effects please contact your doctor immediately:

Cardiovascular collapse (rapid development of circulatory failure), cardiac arrest (failure of the pumping action of the heart, resulting in loss of consciousness and absence of pulse and breathing), respiratory arrest (condition which prevents delivery of oxygen to the body. Lack of oxygen to the brain causes loss of consciousness) or convulsions (uncontrolled shaking of the body).

If you experience any of the following side effects please contact your doctor as soon as possible:

Blurred vision, tremors, nervousness, dizziness or nausea.

XYLOTOX E80-A may cause methaemoglobinaemia (rare blood disorder).

STORING AND DISPOSING OF XYLOTOX E80-A:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

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

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PRESENTATION OF XYLOTOX E80-A:

Tins of 100 x 1,8 ml dental cartridges.

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

IDENTIFICATION OF XYLOTOX E80-A:

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.

REGISTRATION NUMBER:

South Africa: P/4/170

Namibia: NS2 90/4/00185

Botswana: B9300875 S2

NAME AND ADDRESS OF REGISTRATION HOLDER:

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