SCHEDULING STATUS

RSA: S4

Namibia: NS2

PROPRIETARY NAME AND DOSAGE FORM

LIGNOSPAN 2%

Loco-regional anaesthetic for dental use

COMPOSITION

Each cartridge of solution contains	1,8 ml
Lignocaine hydrochloride equivalent to	
Lidocaine (Lignocaine)	36 mg
Adrenaline tartrate equivalent to	
Epinephrine (Adrenaline)	22,5 μg
Antioxidant	
Potassium metabisulphite	2,16 mg

LIGNOSPAN 2% also contains the following inactive ingredients:

Sodium edetate, sodium chloride and water for injection.

PHARMACOLOGICAL CLASSIFICATION

A.4 Local anaesthetics.

PHARMACOLOGICAL ACTION

The solution has a local anaesthetic and vasoconstrictor action of long duration.

INDICATIONS

LIGNOSPAN 2% is indicated for local anaesthesia in dental operations especially those which are considered difficult. It is also suitable for routine dental operations and for use in preparing teeth to support dentures or crown and bridge prosthesis.

CONTRAINDICATIONS

These may be two types:

- Specific allergies to lignocaine and allergies of cross-type procaine-lignocaine.
- Contra-indications to have the vaso-constrict or epinephrine (adrenaline) in arterial hypertension, in certain cardiac disorders, especially coronary disorders.
- Contra-indicated in patients who regularly take tricyclic antidepressant drugs.

  Do not use on patients under MAOI treatment (Mono Amine Oxidase Inhibitors). MAOI inhibits the degradation of epinephrine (adrenaline) in the blood. When anaesthetics containing adrenaline are injected in these patients, occasionally, accidents due to abnormal blood concentrations of the hormone occur.

  In pregnancy: the use of any anaesthetic is not advised unless there are compelling reasons for doing so. In such a case, anaesthetics of the lidocaine (lignocaine) type are considered reasonably safe.

WARNINGS and SPECIAL PRECAUTIONS

Since all local anaesthetics are potentially toxic drugs, the minimum amount of local anaesthetic agent necessary to produce adequate anaesthesia and avoid toxic reactions should be used. Debilitated, malnourished, elderly patients and children should be given reduced doses commensurate with their age and physical status.

DOSAGE AND DIRECTIONS FOR USE

For ordinary use, one cartridge is sufficient to obtain a satisfactory level of anaesthesia provided the injection is made at the site of the intended operation.

In more complicated operations (pulpectomies, multiple extractions where teeth have been affected by parodontitis) one and a half cartridges are sufficient. For block infiltrations the dosage is one and a half cartridges. Do not exceed 2 in general cases.

Dosages should be reduced for elderly or debilitated patients.

For adolescents between 14 and 17, usual dosage of one cartridge.

Do not exceed two in general cases.

For children between 6 and 14, usually dose of three quarters of a cartridges. Do not exceed one and a half cartridges in usual cases.

For children between 3 and 6, between half to one cartridge. Not recommended for children under 3 years of age.

Alternatively, the maximum drug dose may be determined by the application of one of the standard pediatric drug formulae (e.g. Clark's rule or Young's rule).

Body surface area may also be used as a guide in determining drug dosage in pediatric patients. Injections should always be made slowly and with frequent aspirations. If blood is aspirated, the needle must be withdrawn and relocated. Any unused portion of a cartridge should be discarded.

SIDE EFFECTS

The following adverse reactions may occur in response to the epinephrine (adrenaline) component in LIGNOSPAN 2%: fear, anxiety, tenseness, restlessness, throbbing headache, tremor, weakness, dizziness, pallor, respiratory difficulty, and palpitations.
In psychoneurotic individuals, existing symptoms may be aggravated.
Due to the presence of epinephrine (adrenaline), this preparation should be used with extreme caution in patients with cardiovascular disease. Some patients may be less tolerant to lidocaine (lignocaine) hydrochloride or may become sensitized, with a risk of allergic reactions with further usage. Idiosyncrasy has been reported.

The main systemic toxic effect is excitation of the central nervous system, manifested by yawning, restlessness, excitement, nausea and vomiting. This may be followed by depression, muscle twitching, convulsions, respiratory failure and coma. There is simultaneous depression of the cardiovascular system with pallor, sweating and hypotension. Arrhythmia may occur.

Toxic effects may be controlled by stopping administration. Respiratory failure may require assisted respiration. Convulsions may be controlled by a short-acting barbiturate such as thiopentone sodium.

The circulation should be maintained with infusions of plasma or suitable electrolyte solutions. Mephentermine sulfate, methoxamine hydrochloride and phenylephrine hydrochloride have been suggested. Isoprenaline hydrochloride has been suggested for cardiac depression.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See “Side Effects”.

IDENTIFICATION

LIGNOSPAN 2% is a clear, aqueous solution in 1.8 ml cartridges.

PRESENTATION

Cartons containing 50 1.8 ml cartridges.

STORAGE INSTRUCTIONS

Store in a cool (at or below 25 °C) dark place. Do not freeze

Keep out of reach of children.

REGISTRATION NUMBER

RSA: J/4/208

Namibia: 11/4/0200

V

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

The Dental Warehouse (Pty) Ltd

45 Lake Road

Longmeadow Business Estate North

Modderfontein

Johannesburg

1609

DATE OF PUBLICATION OF THE PACKAGE INSERT

8 October 1991

Date of the most recently revised package insert as approved by Council:

2 February 2015