SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Xylocaine 2% w/v with Adrenaline (epinephrine) 1:80,000 DENTAL Solution for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains Lidocaine Hydrochloride equivalent to lidocaine hydrochloride anhydrous 20 mg (44 mg per 2.2 ml cartridge) and Adrenaline (Epinephrine) tartrate equivalent to adrenaline (epinephrine) 12.5 micrograms (27.5 micrograms per 2.2 ml cartridge).

Excipients – contains sodium metabisulphite (E223)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless, sterile aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Xylocaine 2% with Adrenaline 1:80,000 DENTAL is a local anaesthetic solution for use in dental infiltration anaesthesia and all dental nerve block techniques.

4.2. Posology and method of administration

Infiltration - the usual dose is 1 ml.
Nerve block - the usual dose is 1.5 to 2 ml.

The recommended maximum dose for Xylocaine when given with adrenaline is 500 mg.

Children and elderly or debilitated patients require smaller doses.

4.3 Contraindications

Known hypersensitivity to anaesthetics of the amide type.

The use of a vasoconstrictor is contra-indicated for anaesthesia of fingers, toes, tip of nose, ears and penis.

Xylocaine with adrenaline should not be given intravenously.

4.4 Special warnings and precautions for use

In common with other local anaesthetics, Xylocaine with adrenaline should be used cautiously in patients with epilepsy, impaired cardiac conduction, impaired respiratory function, and in patients with impaired hepatic function if the dose or site of administration is likely to result in high blood levels.

Facilities for resuscitation should be available when local anaesthetics are administered.

The effect of local anaesthetics may be reduced if an injection is made into an inflamed or infected area. Solutions containing adrenaline should be used with caution in patients with hypertension, cardiac disease, cerebrovascular insufficiency or thyrotoxicosis.

Solutions containing adrenaline should be used where possible so as to prolong anaesthesia and reduce systemic absorption. This is particularly important in highly vascular areas.

Xylocaine 2% w/v with Adrenaline (Epinephrine) 1:80,000 DENTAL contains Sodium Metabisulfite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm. This may be manifested as a rash, swelling, low blood pressure and breathlessness and may be more prevalent in people with a history of allergies and asthma.

4.5 Interaction with other medicinal products and other forms of interaction

Use with caution in patients taking tricyclic antidepressants, MAOI's or receiving potent general anaesthetic agents.

4.6 Fertility, pregnancy and lactation

Although there is no evidence from animal studies of harm to the foetus, as with all drugs, lidocaine should not be given in early pregnancy unless the benefits are considered to outweigh the risks.

4.7 Effects on ability to drive and use machines

Xylocaine 2% w/v with Adrenaline (epinephrine) 1:80,000 DENTAL has no influence on the ability to drive and use machines.

4.8 Undesirable effects

In common with other local anaesthetics, adverse reactions to Xylocaine with adrenaline are extremely rare in dental practice and are usually the result of excessively high blood concentrations due to inadvertent intravascular injection, excessive dosage, rapid absorption or occasionally to hypersensitivity, idiosyncrasy or diminished tolerance on the part of the patient. In such circumstances systemic effects occur involving the central nervous system and/or the cardiovascular system.

CNS reactions are excitatory and/or depressant, and may be characterised by nervousness, dizziness, blurred vision and tremors, followed by drowsiness, convulsions, unconsciousness and possibly respiratory arrest. The excitatory reactions may be very brief or may not occur at all, in which case the first manifestations of toxicity may be drowsiness, merging into unconsciousness and respiratory arrest.

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

Allergic reactions are extremely rare. They may be characterised by cutaneous lesions, urticaria, oedema or anaphylactoid reactions. Detection of sensitivity by skin testing is of doubtful value.

4.9 Overdose

No data.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anaesthetics, local, amides
ATC code: N01BB02

At high doses lidocaine has a quinidine like action on the myocardium i.e. cardiac depressant. All local anaesthetics stimulate the CNS and may produce anxiety, restlessness and tremors.

5.2 Pharmacokinetic properties

Lidocaine is readily absorbed from the gastro-intestinal tract, from mucous membranes and through damaged skin. It is rapidly absorbed from injection sites including muscle.

Elimination half-life is 2 hours. Lidocaine undergoes first pass metabolism in the liver. Less than 10% of a dose is excreted unchanged via the kidneys.

The speed of onset and duration of action of lidocaine are increased by the addition of a vasoconstrictor and absorption into the site of injection is reduced.

5.3 Preclinical safety data

Lidocaine hydrochloride and adrenaline are both well established active ingredients.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, sodium metabisulfite (E223), hydrochloric acid, sodium hydroxide, water for injections.

6.2 Incompatibilities

None stated.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Store below 25^{o}C.
Keep the container in the outer carton in order to protect from light.

6.5 Nature and contents of container

Glass standard dental cartridges 2.2m1 in boxes of 50 or 100.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Use on one patient during one treatment only.

7 MARKETING AUTHORISATION HOLDER

DENTSPLY Limited
Trading as Dentsply Pharmaceutical
Building 3, The Heights
Weybridge, Surrey, KT13 0NY
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 04690/0032

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15 February 2002

10 DATE OF REVISION OF THE TEXT

16/05/2016