SUMMARY OF PRODUCT CHARACTERISTICS

Product Summary

1. Trade Name of the Medicinal Product

XYLEPAK SPRAY

2. Qualitative and Quantitative Composition

One gram (g) of solution contains:

Lidocaine base 15.00 mg
Cetrimide 0.15 mg

3. Pharmaceutical Form

Metered dose mouth spray without propellant (dosimetric pump with actuator).
OR.M.D.SP.SOL. 15% + 0,15% (w/w)

Clinical Particulars

4.1 Therapeutic Indications

Production of topical anaesthesia and disinfection of the mucous membrane in the buccal cavity, especially :

before the performance of a local or nerve block injection,
prior to the extraction of mobile, deciduous or permanent teeth,
prior to the adjustment and fitting of crowns and bridges or the adjustment of bands in orthodontic treatments,
prior to the lancing of sub-mucosal abscesses,
prior to scaling.

4.2 Posology and Method of Administration

Recommended doses :

1 metered dose containing 10 mg of lidocaine is usually sufficient to achieve anaesthesia on a particular site. Two may be used.

Dosage schedule :

The application of one dose may be repeated in 4 or 5 different areas of the buccal mucosa during the same sitting; but no more than 3 doses should be applied to the same quadrant. Only one quadrant should be anaesthetised during the course of one sitting.

The tip of the nozzle should be placed at about two cm from the area to be anaesthetised. The actuation of the valve emits a dose of spray covering an area of about 1 cm in diameter.

The product may be used on all categories of patients.

However, it should not be used on children under three years of age.

4.3 Contra-Indications

XYLEPAK SPRAY should not be administered to patients known to be hypersensitive to lidocaine and/or cetrimide, or to any of the other components of the product.

4.4 Special Warnings and Precautions for Use

The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions and readiness for emergencies. The lowest dose that results in effective anaesthesia should be used to avoid high plasma levels and serious side effects.
Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age and physical status.

XYLEPAKR SPRAY should be used with caution if there is sepsis or extremely traumatised mucosa in the area of application, since under such conditions there is potential for rapid systemic absorption of both lidocaine and cetrimide.

It should be used with caution in persons with known drug sensitivities.
Avoiding spraying back of throat or mouth is recommended.

4.5 Interactions with other Medicaments and Other Forms of Interaction

Concurrent use of beta-adrenergic blocking agents may slow metabolism of lidocaine because of decreased hepatic blood flow, leading to increased risk of lidocaine toxicity, in particular with large doses, repeated administration, or oral use (especially if swallowed) of lidocaine.

Cimetidine may inhibit hepatic metabolism of lidocaine, leading to increased risk of lidocaine toxicity, in particular with large doses, repeated administration, or oral use (especially if swallowed) of lidocaine.

4.6 Pregnancy and Lactation

Pregnancy

Reproductive studies have been performed in animals without evidence of harm to the animals foetus. However, the safe use of lidocaine in humans has not been established with respect to possible adverse effects upon foetal development. Careful consideration should be given to this fact before administering this drug to women of childbearing potential, particularly during early pregnancy.

Lactation

Problems in humans have not been documented. However, risk-benefit must be considered.

4.7 Effects on Ability to Drive or Use Machines

None stated.

4.8 Undesirable Effects

Should side effects or adverse reactions occur following the use of lidocaine; they may be due either to excessive dosage or to rapid absorption, which both produce high plasma concentrations, or to idiosyncrasy, hypersensitivity, or decreased patient tolerance.

Central nervous system reactions :

CNS reactions are excitatory and/or depressant, and may be characterized 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 system reactions :

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

Treatment of a patient with toxic manifestations consists of assuring and maintaining a patent airway, supporting ventilation with oxygen, and assisted or controlled ventilation (respiration) as required. This usually will be sufficient in the management of most reactions. Should a convulsion persist despite ventilatory therapy, small increments of anticonvulsive agents may be given intravenously. Examples of such agents include benzodiazepine (e.g., diazepam), ultrashort acting barbiturates (e.g., thiopental or thiamylal), or a short acting barbiturate (e.g., pentobarbital or secorbarbital). Cardiovascular depression may require circulatory assistance with intravenous fluids and/or vasopressors (e.g. ephedrine) as dictated by the clinical situation.

Allergic reactions (very unfrequent) :

Allergic reactions may occur as a result of sensitivity to local anaesthetics. Anaphylactoid type symptomatology and reactions, characterized by cutaneous lesions, urticaria, and oedema, should be managed by conventional means. The detection of potential sensitivity by skin testing is of limited value.

At the concentrations used on the skin and mucous membranes (0.1 - 1%), cetrimide does not generally cause irritation, but some patients become hypersensitive to cetrimide after repeated applications.

4.9 Overdose

The normal application of XYLONOR SPRAY according to its directions for use, is very unlikely to result in an overdose. However, in the improbable case that symptoms of an overdose do occur, the procedure for treatment which is described in paragraph 4.8. should be followed.

Pharmacological Properties

5.1 Pharmacodynamic Properties

XYLONOR SPRAY combines two active ingredients :

Lidocaine stabilises the neuronal membranes and prevents the initiation and conduction of nerve impulses, thereby effecting local anaesthesia. It does not contain a paramino group.

Cetrimide is an antiseptic of the quaternary ammonium group with both bactericidal and detergent properties. It has bactericidal activity against gram-positive organisms but is less effective against some gram-negative organisms; strains of Pseudomonas aeruginosa are particularly resistant.

XYLONOR SPRAY allows a topical anaesthesia of the mucous membranes in the oral cavity. The onset of action is
2-5 minutes. The duration of anaesthesia is 10-20 minutes.
This anaesthetic effect is complemented by a disinfectant action.

5.2 Pharmacokinetic Properties

Lidocaine is metabolized mainly in the liver and is excreted by the kidneys.
Approximately 90 % of the lidocaine administered is excreted in the form of various metabolites, while less than 10% is excreted unchanged.
The primary metabolite in urine is a conjugate of 4-hydroxy-2,6-dimethylaniline.

Cetrimide penetrates into the superficial layer of the epidermis.
Absorption through the gastrointestinal tract is poor, more than 90% of the dose ingested is excreted in the faeces.

5.3 Preclinical Safety Data

Not applicable.

Pharmaceutical Particulars

6.1 List of Excipients

Saccharin, natural mint flavour, dipropylene glycol, ethylic alcohol at 95% (v/v).

6.2 Incompatibilities

None stated.

6.3 Shelf-life

3 years.

6.4 Special Precautions for Storage

Store below 25ºC.

6.5 Nature and Contents of Container

Metered dose aerosol containing 36 g of solution.

6.6 Instructions for Use/Handling

The nozzle should be fitted onto the pump before use.

Administrative Data

7. Marketing Authorisation Holder

ADIPHARM Ltd.
Pharmaceutical producer & Distributor
54, Marni St. GR10437 Athens - Greece

8. Marketing Authorisation Number

9. Date of First Authorisation/Renewal of Authorisation

First Authorization: March 2000
Last Renewal: June 2005

10. Date of Revision of the Text

August 2011