Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xylonor 150 mg/g + 1.5 mg/g oromucosal spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of solution contains 150 mg of lidocaine and 1.5 mg of cetrimide
Each actuation delivers approximately a dose of 10 mg of lidocaine and 0.1 mg of cetrimide.

Excipients with known effect: this medicinal product contains 45.45 g of ethanol 96% per 100g of solution.

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray, solution.
Colourless to slightly yellow liquid with an odour of spearmint.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Xylonor is indicated for the 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 band in orthodontic treatments
- prior to scaling
- prior to the lancing of sub-mucosal abscesses

Xylonor is indicated in adults, adolescents and children from aged 6.

4.2 Posology and method of administration

Posology:

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 (40-50 mg) 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 anaesthetized during the course of one sitting.

A dose of 200 mg lidocaine should not be exceeded.

Method of administration

The tip of the nozzle should be placed at about two cm from the area to be anaesthetized. 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 in children under six years of age because of the risk of chocking.

4.3 Contraindications

Hypersensitivity to the active substances, lidocaine and/or cetrimide, or to any excipients listed in section 6.1.

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.

Xylonor 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.

The oropharyngeal use of topical anaesthetic agents may interfere with swallowing and thus enhance the danger of aspiration, particularly in children. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma. In order to avoid burns, it is recommended not to drink or eat hot foods until the effects of Xylonor have worn off.

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per 20 actuations (maximum recommended dose) may be absorbed in the blood.

4.5 Interaction with other medicinal products and other forms of interactions

1. Soaps and anionic surfactants are known to decrease the bactericidal activity of cetrimide.

2. Lidocaine should be used with caution in patients receiving other local anaesthetics or antiarrhythmic drugs.

3. 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.

4. 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 Fertility, pregnancy and lactation

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

Breastfeeding:
Problems in humans have not been documented. Lidocaine like other local anaesthetics may enter breast milk, but in such small quantities that there is generally no risk of affecting the child at therapeutic doses.

4.7 Effects on ability to drive and use machines

Xylonor has no or negligible influence on the ability to drive and use machines.

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 manifestation or 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 short acting barbiturates (e.g., Pentobarbital or Secobarbital). Cardiovascular depression may require circulatory assistance with intravenous fluids and/or vasopressors (e.g. Ephedrine) as dictated by the clinical situation.

Allergic reactions:
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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system :
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

4.9 Overdose

The normal application of Xylonor 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetic for dental use, ATC code: N01BB52

Xylonor 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 metabolised 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin (E954)
Spearmint flavor
Dipropylene glycol
Ethanol 96% (v/v)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

Metered dose aerosol containing 36 g of solution.

Type III glass bottle externally coated with vinyl polychloride.

Elastomer, stainless steel, aluminium and polypropylene pump.

Polypropylene, acetal resin and polyethylene diffuser nozzle.

6.6 Special precautions for disposal and other handling

The nozzle should be fitted onto the pump before use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Septodont
58 Rue du Pont de Créteil
94 107 Saint Maur-des-Fossés
Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA0196/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17 September 1999

Date of last renewal: 17 September 2009

10 DATE OF REVISION OF THE TEXT

March 2019