Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Xylonor, 50 mg/g + 1.5 mg/g, gingival gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of gingival gel contains 50 mg of lidocaine and 1.5 mg of cetrimide.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gingival gel.

White to ivory translucent gel with a mint odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Xylonor is indicated for the production of topical anaesthesia in the buccal cavity, especially in the following procedure:

- Anaesthesia of the mucous membrane before injection, lancing of abscesses, or scaling.
- Surface anaesthesia for the extraction of mobile, deciduous or permanent teeth.
- Prevention of gagging during impression taking.

Xylonor is indicated in adults and in children and adolescents aged 4 to 18 years of age.

4.2 Posology and method of administration

Posology
Recommended doses:
To be used only once from 0.1 - 0.5g gel (2 mm or volume of a rice grain to 1 cm) by topical local application (i.e. 5-25 micrograms lidocaine base).

Under aseptic conditions, extrude about 2 mm (equivalent to approximately 0.1 g) of gel from the tube onto a cotton pellet. Then massage previously dried mucosa.

Depending upon the surface to be anaesthetised and the status of the patient (age, physical condition), the dose of the gel used may be increased, up to 0.5 g.

A dose of 4g gel (200mg lidocaine) must not be exceeded in one session.

Do not use in children under 4 years of age.

Method of administration

Apply gel to previously dried oral mucosa. Subsequent removal of excess saliva with cotton rolls or saliva ejector minimises dilution of the gel and permits maximum penetration.
Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age and physical status (see section 4.4).

4.3 Contraindications

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

Hypersensitivity to local anaesthetics of the amide type.

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.

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.

4.5 Interaction with other medicinal products and other forms of interactions

Soaps and anionic surfactants are known to decrease the bactericidal activity of cetrimide.
Lidocaine should be used with caution in patients receiving other local anaesthetics or antiarrhythmic drugs.
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 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 at the recommended doses.

4.8 Undesirable effects

Systemic adverse reactions are extremely rare with lidocaine ointments. However, as with any local anaesthetic, adverse reactions may result from high plasma levels due to excessive dosage, or rapid absorption, or may result from hypersensitivity, idiosyncrasy or diminished 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 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:
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 anaesthetics, Lidocaine combinations, ATC code: N01BB52

Lidocaine stabilises the neuronal membranes and prevents the initiation and conduction of nerve impulses, thereby effecting local anaesthesia.

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 combines both these ingredients in a non-irritant, water miscible excipient. This gel effects local topical anaesthesia. The onset of action is 2-5 minutes. The duration of anaesthesia is 30-60 minutes. This anaesthetic effect is complemented by a disinfecting 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 flavour
Macrogols 300, 1500 and 4000

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Keep tube tightly closed.

6.5 Nature and contents of container

Aluminium tube internally coated with epoxy varnish, with a polyethylene screw cap. Contents: 15g.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA0196/014/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1999

Date of last renewal: 01 October 2009.

10 DATE OF REVISION OF THE TEXT

October 2019