SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Xylonor Spray, 150 mg/g + 1.5mg/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

Excipient 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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Xylonor Spray 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 bands in orthodontic treatments,
- prior to the lancing of sub-mucosal abscesses
- prior to scaling.

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

4.2 Posology and method of administration

<u>Posology</u>

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 anaesthetized during the course of one sitting.

Method of administration

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 four years of age.

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 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 Interaction with other medicinal products 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 Fertility, pregnancy and lactation

Pregnancy
Reproductive studies have been performed in animals without evidence of harm to the animal's 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.

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

4.7 Effects on ability to drive and use machines

Xylonor Spray may have minor influence on the ability to drive and use machines. Dizziness and blurred vision may occur following administration of the medicinal product (see section 4.8). Patients should not drive or use machines until any such symptoms have completely resolved.

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 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 system reactions:
Cardiovascular reactions are depressant and may be characterised 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, characterised 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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetics, Lidocaine combinations; ATC code: N01BB52

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 grampositive 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.

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 at 96% (v/v)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

Metered dose aerosol containing 36 g of solution

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 Ltd.
Units R & S
Orchard Business Centre,
St Barnabas Close,
Allington, Maidstone
Kent ME16 0JZ
England

8. MARKETING AUTHORISATION NUMBER

PL 08313/0032

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Date of first authorisation: 13/02/1991
Date of latest renewal: 31/03/2010

10. DATE OF REVISION OF THE TEXT

10/2018