Physician's Prescribing Information

Xylonor

1) Name of the medicinal product: XYLONOR

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 is indicated for surface anaesthetic in dentistry.
XYLONOR is indicated in adults, and in children and adolescents aged 6 to 18 years of age.

4.2) Posology and method of administration:
Instructions for use: One metered dose delivers approximately 10 mg of lidocaine.
The atomizer nozzle should be placed at about 2 to 4 cm from the area to be anaesthetized. Spray droplets of solution so as to cover an area of about 1 cm in diameter. The application of one dose may be repeated on to 4 or 5 different areas of the oral mucosa during the same session.
In order to limit the nauseous reflex, pulverize on or several doses of solution towards the palate.
Do not exceed to pulverizations per session.
Method and route of administration: Local use only. Gingival route.
Before using the atomizer, adjust the diffuser nozzle to the pump, then press vertically three times to prime the pump.
The maximum dose should not exceed 1.6 g of solution, i.e. 20 pressures per session.

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.

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 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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il /

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
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 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: 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: 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: The expiry date of the product is indicated on the label and packaging. Do not use after the expiry date.
Shelf life after first opening: 9 months.

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.
Box containing 1, 2 or 3 aerosol sprays. Not all pack sizes may be marketed.

6.6) Special precautions for disposal: 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) Israeli drug registration number: 119-53-23284-00

8) Manufacturer: Septodont, Saint-Maur-Des-Fossés, France.

9) Israeli marketing authorization holder: A. Levy Dental Co. Ltd., VAT # 510917768, 27 Kalisher Street, Tel Aviv 6516506, Israel.

10) REVISED ON: 12/2020
[XYLNR-SPRY-DCTR-12/20 dated 03/12/2020]

SEPTODONT
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés
France