Physicians Prescribing Information

XYLONOR, Solution for dental use in atomizer

IDENTIFICATION OF THE PORDUCT

Qualitative and Quantitative Composition:
Active ingredients: Lidocaine 15.00 g + Cetrimide 0.15 g
Excipients: Saccharin, natural mint flavour, dipropylene glycol, alcohol q.s. as 100 ml of solution for dental use.
One metered dose contains 10 mg of lidocaine.

Dosage form: Solution for dental use. 36 gram in an atomizer.

Pharmacotherapeutic class: LOCAL ANAESTHETIC FOR DENTAL USE. (N: Central nervous system)

Therapeutic Indications: Topical anaesthesia for: infoltration anaesthesia, fitting and adjusting of crowns and bridges abutment, juxta-gingival and sub-gingival scaling.

WARNING !
Not to be used in case of (contraindications):
This medicine SHOULD NOT BE USED in the following cases:
- Children under 6 years of age, because of a risk of wrong way in case of use by pulverizations.
- Patients allergic to one of the ingredients, particularly to lidocaine (local anaesthesic) or to cetrimide (antiseptic).

IN CASE OF A DOUBT, CONSULT YOUR DENTIST.

Special warnings:
- Risk of unintentional biting trauma to the lips, cheek, mucosae or tongue when these structures are anaesthetized.
- The maximum dose should not exceed 1.6 g of solution, i.e. 20 pressures per session. Take into account the possible resorption of lidocaine which may be more important and quicker in case if injured oral mucosa.
- Use with caution in patients with traumalize mucosa and/or sepsis in the region of the proposed application.
- The oropharyngeal use of topical anaesthetic agents may interfere with swalloing and thus enhance the danger of aspiration. This is particularly important in children because of their frequency of eating. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma. Therefore prevent ingestion of food 60 minutes. Avoid contact with the eyes.
- See to it that the anaestheitc is limited to the area to be treated, particularly when spraying. Inadvertently dispencing the anaesthetic towards the ovula or the pharynx may result in a transient oaralysis of them which is temporarly bothersome for the patient. It is resorbed quickly.

Precautions while using the medicine:
After the anaesthetic agent is applied to the mucosa, it is important that the patient should spit out the surplus of product so as to avoid swallowing it.
IN CASE OF DOUBT, CONSULT YOUR DENTIST.

Use in preganacy: Lidocaine crosses the placental barrier and may be taken up by fetal tissues. No specific disturbances to the productive process have so far been reported. E.g., increased incidense of malformations or other direct or indirect harmful effects on the fetus, but safelt for use during pregnancy has not established, therefore use only when potential benefits outweight the unknown potential hazards to the fetus.

Use during lactation: Lidocaine enters the mothers milk, but in such small quintities that there is generally no risk for the child being affected at the therapeutic dose levels.

Sportspeople: Sportspeople should be warned that this drug contains an active ingredient likely to induce a positive reaction to tests undertaken during antidoping controls.

List of excipients, the knowledge of which is neccesary for being used safely in certain patients: Propylene glycol.

PROPER USE OF THIS MEDICINE
Instructions for use: One pressure delivers approximately 10 mg of lidocaine.
The atomizer nozzle should be placed at about 2 to 4 cm from teh area to be anaesthized. Soray 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, pulvorize 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.

Overdose: In normal conditions of densitry no overdosage effect has ever been reported. Although, should a sode over the prescribed ones be applied, cardiovascular or neurologica toxicity manifistations may occur and should then be treated by injecting an ultra-short acting barbiturate or a benzodiazepine and by assisted controlled ventilation with oxygen.

UNWANTED OR UNCONFORTABLE EFFECTS (SIDE EFFECTS):
LIKE ANY OTHER ACTIVE INGREDIENT, THIS MEDICINE IN SOME PATIENT ENTALE MORE OR LESS BOTHERSOME EFFECTS:
- Risk of allergy
- Toxic reactions, evidence of topical anaesthetic overdisage in blood. May occur either immediately, due to an inadvertent intravascular injection, or later by an excessive amount of local anaesthetic drug.

Clinical signs of overdosage:
On the central nervous system: nervousness, restlessness, yawning, tremors, headache, apprehension, nystagmus, logorrhea, nausea, tinnitus.
When these signs appear, it is necessary to initiate immediate corective measure so as to prevent any possible worsening of the patient state.
On the respiratory system: tachypnea, then bradypnea, which may result in apnea.
On the cardiovascular system: bradycardia, drop in cardiatic output and in blood pressure.

DO NOT HESSITATE TO REFER TO YOUR DENTIST AND TO REPORT ANY UNWANTED OR BOTHERSOME EFFECT THAT IS NOT MENTIONED IN THE LEAFLET.

Shelf-life: Do Not use after the expiry date mentioned on the outer package.
Special storage precautions: Should be stored below 25ºC.

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Importer: A. Levy Dental Company Ltd., 27 Kalisher street, Tel-Aviv 65165
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