Package leaflet: Information for the user

Xylonor 50 mg/g + 1.5 mg/g gingival gel
Lidocaine and Cetrimide

Read all this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or dentist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or dentist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xylonor is and what it is used for

Local anaesthetic.

Xylonor contains lidocaine, an anaesthetic agent which stabilises the neuronal membrane 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.
Xylonor allows a topical anaesthesia in the buccal cavity.

Xylonor is used for production of topical anaesthesia in the buccal cavity.

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

2. What you need to know before you use Xylonor

Only a dentist or stomatologist can administer this product.

Do not use Xylonor:

- if you are allergic to lidocaine and cetrimide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to local anaesthetics of the amide type.

Warnings and precautions
Talk to your doctor, pharmacist or dentist before using Xylonor, if you have an infection or inflammation or extremely traumatised mucosa in the area to be anaesthetised.

Take special care with Xylonor in debilitated, elderly patients, acutely ill patients and children. In these cases, reduced doses should be given, commensurate with the age and the physical status of the patient.

Children and adolescents
Particular care should be taken when treating children and adolescents.
Your dentist will adjust the dosage according to the child's age and weight.
Do not use in children under 4 years of age.

Other medicines and Xylonor
Tell your doctor, pharmacist or dentist if you are taking or have recently taken or might take any other medicines, even those not prescribed.

- other local anaesthetics or antiarrhythmic drugs
- beta-adrenergic blocking agents which may slow metabolism of lidocaine because of decreased hepatic blood flow
- cimetidine (drugs against stomach ulcer) which may inhibit hepatic metabolism of lidocaine.

Tell your dentist if you have injuries in your mouth because lidocaine may be released into the blood and interact with other medicines.

Xylonor with food and drink
After using this medicine, avoid chewing gum or eating until normal sensation is restored, otherwise you risk biting your lips, cheeks or tongue.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or dentist for advice before taking this medicine.

This product can be used during pregnancy and breastfeeding without any risk to the foetus or to the breastfed child, provided that it is used as prescribed.

No effects on fertility are anticipated.

Driving and using machines
This product has no or negligible influence on the ability to drive and use machines.

3. How to use Xylonor

The stomatologist or dentists are only authorised to use Xylonor because they are trained in local anaesthesia techniques and their complications.

However, your doctor or dentist may decide to administer a smaller or greater amount of Xylonor. He will adjust the posology according to your age, weight, health condition and to the surface to be anaesthetised. The minimum effective anaesthetic dose should be used.

If you have the impression that the effect of Xylonor is too strong or too weak, talk to your doctor, pharmacist or dentist.

Your dentist will apply the product to the area to be numbed using a cotton ball.

If your dentist or stomatologist use more Xylonor than they should
Under normal conditions of use in dentistry, no overdose effects are to be expected with a product for local use only.

However, the following symptoms may be signs of toxicity due to excessive doses or rapid absorption of the product: burning, pricking, tingling sensations around the mouth with no apparent physical cause,

dizziness, nervousness, anxiety, apprehension, euphoric mood, confusion, drowsiness, oversensitivity of hearing, ringing in the ears, blurred vision, vomiting, nausea, feeling hot, cold or numbed, muscle twitching, tremors, fits, loss of consciousness, abnormally slow breathing or suspension of breathing, abnormally slow or irregular heartbeat, low blood pressure, or cyanosis of the nail beds and lips, fatigue and weakness (which are clinical sign of methemoglobinemia).

If you experience any of these, talk to your dentist, doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your dentist, doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

While you are in the dentist's office, your dentist will carefully monitor the effects of Xylonor.

Inform your dentist, doctor or pharmacist immediately if you experience one of the following serious side effects, which might be symptoms of a hypersensitivity reaction (allergic / allergic-like reaction):
- Rash, itching, hives, swelling of the face, lips, gums, tongue and/or throat and difficulty breathing, wheezing, asthma.

Other side effects may also occur in some patients (frequency not known (cannot be estimated from the available data)):
- Rash, redness
- Itching
- Exfoliation and ulceration of the gums
- Abnormal sensation in and around the mouth
- Swelling of the application site, application site burn
- Elevated level of methemoglobin in the blood (methemoglobinemia).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or dentist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Xylonor

Keep this medicine out of the sight and reach of children.
Do not store above 25°C.
Keep the tube tightly closed.

Do not use this medicine after the expiry date which is stated on the label, the carton and the tube after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the gel does not appear white to ivory translucent, with a mint odour or seems deteriorated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xylonor contains
- The active substances are: lidocaine 50 mg and cetrimide 1.5 mg per gram.
- The other ingredients are: saccharin, spearmint flavour, macrogol 300, macrogol 1500, macrogol 4000.

What Xylonor looks like and contents of the pack
Xylonor is a gingival gel, white to ivory translucent with a mint odour.
Xylonor is packaged in aluminium tubes internally coated with epoxy varnish, with a polyethylene screw cap.
The marketing presentation is a tube containing 15 g of gel.

Marketing Authorisation Holder and Manufacturer
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58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés
FRANCE

This leaflet was last revised in

The following information is intended for healthcare professionals only:

For professional use by dentists and stomatologists only.

Posology

For all populations, the lowest dose leading to effective anaesthesia should be used. The necessary dosage must be determined on an individual basis.

- *Adults*

The recommended dose is 0.10 g to 0.20 g of gel (about the size of a small hazelnut) to cover an area of about 1 cm² to 2 cm², corresponding to 5 to 10 mg of lidocaine.
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.
The maximum daily administration of the medicinal product should not exceed 4 g, equivalent to 200 mg of lidocaine.

- *Paediatric population (from 4 years of age)*

The recommended dose is 0.10 g to 0.20 g of gel (about the size of a small hazelnut) to cover an area of about 1 cm² to 2 cm², corresponding to 5 to 10 mg of lidocaine.
The maximum daily administration for a paediatric population should not exceed 4 mg/kg of lidocaine.

- *Elderly patients or patients with hepatic function disorders*

When liver activity is reduced, the minimum effective anaesthetic dose should be used when applied before anaesthetic injection.

Method of administration

The medicinal product is for gingival use (local use) and can be occasionally used by oromucosal route.
Prior to use, the area of administration should be thoroughly dried.

Just before the procedure, a cotton bud should be impregnated with the medicinal product and applied on the mucosa.
Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age and physical status (see section 4.4 of the SmPC).
The total dose of all administered local anaesthetics should not exceed the lowest maximum recommended dose of each local anaesthetic (see sections 4.4 and 4.5 of the SmPC).

Overdose

At normal doses and under normal conditions of administration, overdose is unlikely to occur with a product for local use only.
However, caution should be taken when using the product in association with injectable local anaesthetics, as the risk of CNS toxicity and cardiovascular toxicity may occur with high plasma levels of lidocaine due to excessive dosage, or rapid absorption.
To date, no cases of overdose have been reported when the topical products were used alone.

Symptomatology:

The following reactions may occur with high plasma levels of lidocaine due to excessive dosage or rapid absorption, in particular when associated with the use of injectable local anaesthetics:

Central Nervous System (CNS):
High plasma levels may cause CNS stimulation (including seizures) followed by CNS depression (including respiratory arrest) and may be characterized by the following signs and symptoms of escalating severity: circumoral paresthesia, light-headedness, nervousness, anxiety, apprehension, euphoria, confusion, dizziness, drowsiness, hyperacusis, tinnitus, blurred vision, vomiting, nausea, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations (e.g., twitching, tremors, and convulsions) may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Cardiovascular System:
The cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, arrhythmia and cardiovascular collapse, which may lead to cardiac arrest. Hypertension, tachycardia and angina may be caused by concomitant use with an injectable local anaesthetic containing adrenaline.
Overdose can rarely lead to methemoglobinemia, the clinical signs are cyanosis of the nail beds and lips, fatigue and weakness.

Treatment of overdose:

The availability of resuscitation equipment should be ensured before the onset of dental anaesthesia with local anaesthetics.
If signs of acute toxicity are suspected, the medicinal product should be rinsed away immediately.
Oxygen should be administered rapidly, and assisted ventilation used if necessary. The patient’s position should be changed to supine if necessary.
In cases of cardiac arrest, cardiopulmonary resuscitation should be immediately initiated.
In case of methemoglobinemia, if methemoglobinemia does not respond to administration of oxygen, administration of methylene blue intravenously 1-2 mg/kg body weight over a 5-minute period is recommended.