

Package leaflet: Information for the user

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

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
2. What you need to know before you use Xylonor
3. How to use Xylonor
4. Possible side effects
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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. Cetrимide 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

Do not use Xylonor :

- if you are allergic to lidocaine and cetrимide 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 gel.

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.
- if there is sepsis or extremely traumatised mucosa in the area of application.
- in persons with known drug sensitivities.

Children

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 any other medicines, even those not prescribed.

- soaps and anionic surfactants known to decrease the bactericidal activity of cetrимide
- 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.

Xylonor with food and drink

In order to avoid burns, it is recommended not to drink or eat hot food until effects of Xylonor have worn off.

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.

The administration to pregnant women should be carried out with caution.

Because of the lack of studies relating to the excretion in human milk, the administration should be carried out with caution.

Driving and using machines

Because of the used doses, adverse effects are unlikely.

3. How to use Xylonor

Always use Xylonor exactly as your doctor, pharmacist or dentist has told you. Check with your doctor, pharmacist or dentist if you are not sure.

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

Only one dose (from 0.1 - 0.5 g gel) must be used. In one session, 4 g of gel must not be exceeded.

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.

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

If you use more Xylonor than you should

If the physician or dentist uses more Xylonor than they should, symptoms of overdose can appear:

- Central Nervous System manifestations:
nervousness, dizziness, blurred vision and tremors, followed by drowsiness, convulsions, unconsciousness and possibly respiratory arrest.
- Cardiovascular manifestations:
hypotension, myocardial depression, bradycardia and possibly cardiac arrest.

Instructions:

- assuring and maintaining a patent airway
- supporting ventilation with oxygen
- assisted or controlled ventilation as required
- Should a convulsion persist despite ventilatory therapy, small increments of anticonvulsive agents may be given intravenously:
 - benzodiazepine (e.g., Diazepam)
 - ultrashort acting barbiturates (e.g., Thiopental or Thiamylal)
 - short acting barbiturates (e.g., Pentobarbital, Secobarbital)
- Cardiovascular depression may require circulatory assistance with intravenous fluids and/or vasopressors (e.g., Ephedrine)

4. Possible side effects

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

Nervous manifestations: nervousness, dizziness, blurred vision, tremors, drowsiness, convulsions, unconsciousness, respiratory arrest.

Cardiovascular manifestations: slowing of the heart rate, hypotension, myocardial depression, cardiac arrest.

General manifestations: allergic reactions characterised by cutaneous lesions, urticaria and oedema.

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

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@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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For any information about this medicinal product, please contact the local representative of the marketing authorisation holder.

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