Package leaflet: Information for the user

Xylonor
150 mg/g + 1.5 mg/g
Oromucosal spray solution

Lidocaine/ Cetrimide

Read all of 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, please 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
5. How to store Xylonor
6. Contents of the pack and other information

1. What Xylonor is and what it is used for

Local anaesthetic.
Oromucosal spray, solution containing 36g of solution.

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 of the mucous membrane in the oral cavity.

Xylonor is used for production of topical anaesthesia and disinfection of the mucous membrane in the buccal cavity.

Xylonor is indicated in adults, adolescents and children from aged 6.

2. What you need to know before you use Xylonor

Do not use Xylonor spray
- if you are hypersensitive (allergic) to lidocaine and/or cetrimide or to any of the other ingredients of this medicine (listed in section 6).
- in children under 6 years of age.

Warnings and precautions

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.

Do not spray back of throat or mouth.

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 cetrimide
- 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.

Xylonor contains small amounts of ethanol (alcohol), less than 100 mg per 20 actuations (maximum recommended dose) may be absorbed in the blood.

3. How to use Xylonor

Always use Xylonor exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

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

The application of one dose may be repeated in 4 or 5 (40-50 mg) different areas of the buccal mucosa during the same sitting; but not more than 3 doses should be applied to the same quadrant. Only one quadrant should be anaesthetised during the course of one sitting.

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 type of surgery to be performed.

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

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 medicine 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 notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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
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 out of the sight and reach of children.
Do not store above 25°C.

Do not use Xylonor after the expiry date which is stated on the label, the carton and the bottle after EXP.

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 spray contains

- The active substances are: lidocaine 10 mg per dose and cetrimide 0.10 mg per dose.
- The other ingredients are: saccharin, spearmint flavour, dipropylene glycol and ethanol 96% v/v.

What Xylonor looks like and contents of the pack
Xylonor is a colourless to slightly yellow liquid with an odour of spearmint.

Xylonor is packaged in type III glass bottles externally covered by vinyl polychloride with a pump and a diffuser nozzle.

The marketing presentation is an oromucosal spray, solution containing 36 g of solution.

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

For any information about this medicinal product, please contact the local representative of the marketing authorisation holder.

Septodont Ltd
Unit R & S - Orchard Business Centre
St Barnabas Close
ALLINGTON, Maidstone
KENT ME16 OJZ
UNITED KINGDOM

This leaflet was last revised in:

SEPTODONT
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France
Tel.: 33 (0)1 49 76 70 00