

Xylonor gel

lidocaine, cetrimide

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

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, ask your dentist, doctor or pharmacist.
- 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 dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What XYLONOR GEL is and what it is used for
2. What you need to know before you use XYLONOR GEL
3. How to use XYLONOR GEL
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1. What XYLONOR GEL is and what it is used for

XYLONOR GEL is used to obtain a local anaesthesia of the lining of the inside of the mouth (buccal mucosa) before performing dental procedures.

It contains two active ingredients:

- lidocaine, a local anaesthetic, which numbs the painful area temporarily,
- cetrimide, an antiseptic, which kills any microorganisms that are present.

XYLONOR GEL is for children over 4 years old and adults.

2. What you need to know before you use XYLONOR GEL

Only a dentist or stomatologist can administer this product.

Do not use XYLONOR GEL

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

Warnings and precautions

Talk to your dentist or stomatologist before using XYLONOR GEL if you have a severe infection or an inflammation in the area to be treated.

Other medicines and XYLONOR GEL

Tell your dentist if you are taking, have recently taken or might take any other medicines.

Tell your dentist if you have injuries in your mouth because

lidocaine may be released into the blood and interact with other medicines.

XYLONOR GEL with food and drinks

After using this medicine, avoid chewing gums or any type of food as long as the anaesthesia persists, as there is a risk of 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 dentist for advice before using 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

XYLONOR GEL has no or negligible influence on the ability to drive and use machines.

3. How to use XYLONOR GEL

Only dentists and stomatologists are trained to use XYLONOR GEL.

Your dentist will explain to you why you are being treated with XYLONOR GEL.

He or she will adjust the dosage depending on the treatment you are having, your age and your health.

The usual dose of XYLONOR GEL is 100 to 200 mg (about the size of a small hazelnut of gel). The minimum effective anaesthetic dose should be used.

Your dentist will apply it with a cotton pellet to the buccal mucosa.

Use in 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.

A lower dose than usual may be used in patients who are ill or weak and in children or the elderly.

If your dentist uses more XYLONOR GEL than he or she should

If you swallow a lot of gel, or if you think your child has swallowed any of the gel, tell your dentist.

While you are in your dentist's office, your dentist will carefully follow the effects of XYLONOR GEL.

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.

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 medicine, 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 GEL.

Immediately inform your dentist, doctor, or pharmacist 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 (frequency 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.

Reporting of side effects

If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store XYLONOR GEL

Keep this medicine out of the sight and reach of children.

It is most unlikely that you will be asked to look after this medicine.

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

Do not store above 25°C. Store in a dry place. Keep the tube tightly closed.

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 GEL contains

- The active substances are lidocaine 50 mg/g and cetrimide 1.5 mg/g.
- The other ingredients are spearmint oil, saccharin (E954) and macrogol.

What XYLONOR GEL looks like and content of the pack

It is a white clear gel with an odour of mint.

XYLONOR GEL is available in tube of 15 g.

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