

Package leaflet: Information for the patient

Xylonor gel 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, 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
4. Possible side effects
5. How to store Xylonor Gel
6. Contents of the pack and other information

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 antiseptics, which kills any microorganisms that are present.

Xylonor Gel is for children over 4 years old and adults.

Only a dentist can administer this product.

2. What you need to know before you use Xylonor Gel

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.
- in children under 4 years old.

Warnings and precautions

Talk to your doctor, dentist or pharmacist before using Xylonor Gel

- Soaps should be used with caution when you receive Xylonor Gel, as they can decrease the efficiency of the active substance cetrimide.
- If you have a severe infection or an inflammation in the area to be treated.
- The dentist will adapt the dosage to your age and general condition.
- The dentist should have available resuscitation equipment for effects on heart.

Other medicines and Xylonor Gel

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

Xylonor Gel with food

Avoid chewing gums or any type of food as long as the anaesthesia persists, as there is a risk of biting.

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.

Driving and using machines

Xylonor Gel has no or negligible influence on the ability to drive and use machines.

Using Xylonor Gel and sport

There is a possibility of positive results on doping tests performed on sportsmen.

3. How 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.

The usual dose of Xylonor Gel is 100 to 500 mg (about 2 to 10 mm of gel).

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

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.

The administration of Xylonor Gel may cause high plasma levels in active substances (lidocaine and/or cetrimide), especially excessive dosage or rapid absorption. Symptoms include: effects on your senses (hearing, sight, behaviour), effects on your heart and blood vessels, effects on your immune defences (diminished tolerance).

4. Possible side effects

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

Immediately inform your dentist, doctor or pharmacist if you experience one of the following serious side effects:

- **Effects on your skin:** severe allergic reactions (anaphylactoid reactions) characterized by rash, itching, swelling of the face, lips, gums, tongue, and/or throat and difficulty breathing.
- **Effects on your heart and blood vessels:** low blood pressure, failure of the heart to contract effectively (myocardial depression), abnormally slow heartbeat, and possibly cardiac arrest,
- **Effects on your lungs:** abnormally slow and shallow respiration, which may lead to respiratory arrest.

Other side effects not listed above may also occur:**Not Known (frequency cannot be estimated from the available data):**

- **Effects on your skin:** skin irritation

The following very rare side effects affect 1 of 10,000 patients treated:

- **General effects:** unconsciousness, convulsions, dizziness, drowsiness, feeling nervous
- **Effects on your senses:** blurred vision, trembling

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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If more PILs are necessary, call free number 0800435155.