

Package leaflet: Information for the user

Xylonor Spray, 150 mg/g + 1.5mg/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, ask your dentist, doctor or pharmacist.
- 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.

In this leaflet:

1. What Xylonor Spray is and what it is used for
2. What you need to know before you use Xylonor Spray
3. How to use Xylonor Spray
4. Possible side effects
5. How to store Xylonor Spray
6. Contents of the pack and other information

1. What Xylonor Spray is and what it is used for

Xylonor Spray is used to obtain a local anaesthesia of the lining of the inside of the mouth (buccal mucosa).

It contains two active ingredients:

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

Xylonor Spray 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 Spray

Do not use Xylonor Spray

- if you are allergic (hypersensitive) to one of the active ingredients (lidocaine or cetrimide) or to 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.

Warning and precautions

- Before receiving this medicine, tell your dentist if you have 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.
- The dentist should avoid spraying the back of the throat.

Other medicines and Xylonor Spray

Tell your dentist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

Your dentist should take special attention if you are taking the following medicines:

- medicines used to reduce your blood pressure (e.g. betablockers),
- medicines used to treat ulcers (e.g. cimetidine).

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 taking this medicine.

Driving and using machine

If you experience side effects, including dizziness or blurred vision, do not drive or use machines until these symptoms have disappeared.

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

3. How to use Xylonor Spray

Your dentist will explain to you why you are being treated with Xylonor Spray.

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

One to two metered doses are usually sufficient to achieve anaesthesia on a particular site. Your dentist will spray it onto the buccal mucosa.

Xylonor Spray should not be sprayed in the back of throat or mouth.

If your dentist uses more Xylonor Spray than he or she should

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

4. Possible side effects

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

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

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

- skin rash, hives or itching in the mouth, skin irritation and occasionally sensitisation: these might be symptoms of an allergic (hypersensitivity) reaction
- swelling of the face, lips, tongue and/or throat, difficulty breathing: these might be symptoms of a severe allergic (anaphylactoid) reaction.

These side effects happen very rarely (they may affect up to 1 in 10,000 people).

Other side effects not listed above may also occur in some patients.

The administration of Xylonor Spray 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).

The following side effects may be observed:

- **Effects on your heart and blood vessels:** low blood pressure, slow or irregular heartbeats, which may lead to cardiac arrest,
- **Effects on your lungs:** abnormally slow and shallow respiration, which may lead to respiratory arrest,
- **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 Spray

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.

Your dentist will not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Your dentist will keep it up to 25°C.

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%.

What Xylonor Spray looks like and content of the pack

It is a clear, colourless to slightly yellow liquid with an odour of mint.

Xylonor Spray is available in metered dose aerosol containing 36 g of solution.

Marketing authorisation holder

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This leaflet was last revised in October 2018.

If more PILs are necessary, call free number 0800435155.