Package leaflet: Information for the user

Xylocaine 100 mg/ml, Spray
Lidocaine

Read the entire 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.
- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Xylocaine 100 mg/ml Spray and what is it used for?
This medicine belongs to the group of local anesthetics. It contains lidocaine, a short-acting local anesthetic of the amide type with a rapid onset of action.

This medicine is used in adults and children aged 2 years and older:
- in all cases where rapid anesthesia of the mucous membrane is required, especially in procedures in otorhinolaryngology, obstetrics, oral surgery, and trauma medicine.
- for pain, burning, itching, and other unpleasant sensations associated with conditions of the skin and mucous membranes.

2. When should you not use this medicine or be extra careful?

When should you not use this medicine?
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- You are allergic to other local anesthetics of the amide type.

When should you be extra careful with this medicine?
- if you are taking medications for heart rhythm disorders (see also the section 'Are you taking any other medicines?') and if you suffer from the metabolic disease porphyria
- if the mucous membranes in the area where the spray is used are damaged, or if there are inflammations in that area
- if your throat is numbed with this agent. It is better not to eat or drink until the numbness has worn off. Otherwise, you may choke or bite your tongue or cheek while your oral cavity is still numb.
- if you are an elderly patient
- if you are in poor general condition
- if you are in a severe state of shock
- if you suffer from epilepsy
- if you suffer from heart rhythm disorders

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- if you suffer from heart failure or other problems with your heart and blood vessels
- if you suffer from liver or kidney disorders
- if there is a risk that this agent will be sprayed into your eyes. If the liquid accidentally gets into an eye, you must immediately rinse the eye with water or a,9% sodium chloride solution.

Contact your doctor or pharmacist before using this medicine.

Are you taking any other medicines?
Are you using any other medications alongside Xylocaine 100 mg/ml Spray, have you done so recently, or are you planning to do so soon? Then tell your doctor or pharmacist. This also applies to medications for which you do not need a prescription.

This medication should be used with caution if you are also being treated with other local anesthetics or medications with a similar structure (such as some antiarrhythmic drugs). It may be necessary for your doctor to adjust the dosage.

What should you pay attention to with food and drink?
If your throat is numbed with this medication, it is better not to eat or drink until the numbness has worn off. Otherwise, you may choke or bite your tongue or cheek while your oral cavity is still numb.

Pregnancy and breastfeeding
Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using any medications.
You can be treated with this medication during pregnancy and the breastfeeding period. In usual dosages, there is generally no risk to the child.

Driving and using machines
Use of this medicine can temporarily affect reaction time in some cases. Keep this in mind if you are going to participate in traffic.

Xylocaine 100 mg/ml Spray contains ethanol
This medication contains 24.1 mg of alcohol (ethanol) per dose, equivalent to 241 mg/ml. This medication can cause a burning sensation on your skin if your skin is damaged.

3. How do you use this medication?
The doctor will administer this medication to you. He will adjust the dosage according to the nature of the procedure, the duration of the procedure, your age, and physical condition.
Are you unsure about the correct use? Then contact your doctor or pharmacist.

Use in adults
The recommended dosage is 1-20 sprays. The maximum dosage depends on the duration of the procedure.

Use in the elderly
Dosages in debilitated or elderly patients should be consistent with their physical condition.

Use in children from 12 years
For children weighing less than 25 kg, the maximum dosage is lower and should be adjusted to the child's weight and physical condition.

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Use in children from 2 to 12 years
The maximum dose for children should be calculated based on mg/kg body weight. When applying Xylocaine 100 mg/ml Spray in the esophagus and trachea, the maximum dose is 3 mg/kg, and when applied in the nose, mouth, or throat, a dose of 4-5 mg/kg should not be exceeded.
Use in children under 2 years
For babies and toddlers under 2 years, Xylocaine 100 mg/ml Spray is not suitable, and less concentrated lidocaine solutions are recommended.

Have you used too much of this medicine?
Symptoms
This medicine is usually administered in the operating room or in the treatment room at the outpatient clinic. You will be closely monitored. Overdose is not expected.

If there is an overdose, you may notice this by the following symptoms:
- yawning
- restlessness
- dizziness
- nausea
- vomiting
- problems with speaking
- problems with hearing
- problems with seeing
- disturbance of your balance or your movement coordination.

These symptoms may be followed by decreased consciousness, reduction in strength, depth and frequency of breathing, and coma.
If you have been administered a very large amount of this medicine, as a result of reduced contractility of the heart and delayed conduction, (sudden) low blood pressure and loss of consciousness can be expected (cardiovascular collapse), followed by cardiac arrest.

What should you do then?
Notify the doctor immediately.

Have you forgotten to use this medicine?
This medicine is usually administered in the operating room or in the treatment room at the outpatient clinic. It is not expected that they will forget to administer this medicine to you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

If you stop using this medicine
After administration of this medicine, the effect sets in quickly and the anesthetic effect lasts about 10-15 minutes (depending on the administered amount). When the anesthesia wears off, you may experience pain as a result of the procedure. Your doctor will inform you on how best to manage the pain in that case.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects
Like any medicine, this medicine can also have side effects. Not everyone experiences them. Side effects can occur more or less frequently, with the following definitions applying:

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Very common: Occurs in more than 1 in 10 users
Common Occurs in 1 to 10 out of 100 users
Uncommon: Occurs in 1 to 10 out of 1,000 users
Rare: Occurs in 1 to 10 out of 10,000 users
Very rarely occurring: Occurs in less than 1 out of 10,000 users
Not known: Frequency cannot be determined from available data

The following side effects have been reported:
Sometimes occurring side effects
- hypersensitivity reaction

Not known
- severe allergic reaction to certain substances, characterized by a significant drop in blood pressure, pallor, restlessness, weak rapid pulse, clammy skin, and reduced consciousness due to sudden strong vasodilation (anaphylactic shock)
- loss of voice
- hoarseness
- sore throat
- irritation at the site where this medicine is used.

Symptoms of overdose if more active ingredient than usual is absorbed into the body.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How should you store this medicine?
Store below 25°C. Cloudiness may occur at temperatures below 8°C, which dissolves at room temperature. Store upright.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the label and the box after "EXP:". It includes a month and a year. The last day of that month is the expiry date.

Do not use this medicine if you notice that the color of the liquid changes or if it becomes cloudy.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal ensures they are destroyed correctly and do not enter the environment.

6. Contents of the package and other information
What substances are in this medicine?
- The active substance in this medicine is: lidocaine base (100 mg per ml). One spray contains 10 mg lidocaine base.
- The other substances in this medicine are: ethanol (96%), macrogol 400, banana flavor (85509/H, Givaudan), levomenthol, saccharin, purified water.

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What does Xylocaine 100 mg/ml Spray look like and what does the package contain?
A spray consists of a glass bottle with a dosing pump. The package also contains a plastic dosing valve for single use.

Xylocaine pump spray is available in packages of 50 ml solution.

Each package contains approximately 500 sprays.

Marketing authorization holderfor placing on the market and
manufacturerant Marketing authorization holder/repacker
Eureco-Pharma B.V.
Boelewerf 2,
2987 VD Ridderkerk

Manufacturer
Aspen Bad Oldesloe GmbH
Industriestraße 32-36
23843 Bad Oldesloe
Germany

Registered under
Xylocaine 100 mg/ml, Spray
RVG 127178//07831 L.V.H: Germany

This product is registered in Germany under the name:
Xylocain Pumpspray, 10 mg/Sprühstoβ

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The following information is intended only for healthcare professionals:

GENERAL
For complete information regarding: pregnancy and breastfeeding, influence on driving ability and the ability to use machines, side effects, overdose, pharmacological properties, shelf life, instructions for use and processing instructions: consult the SPC text.

This text is available from Aspen Pharma Trading Limited, tel. +31 207 095 007.

QUALITATIVE AND QUANTITATIVE COMPOSITION
Xylocaine, spray contains 100 mg lidocaine per milliliter.
One spray contains 10 mg lidocaine base.
For the full list of excipients, see section 6.1 of the SPC.

CLINICAL DATA Therapeutic indications
All cases where rapid and reliable anesthesia of the mucous membrane is required, especially in procedures in otorhinolaryngology, obstetrics, oral surgery, and traumatology.

Xylocaine 100 mg/ml Spray can also be used prophylactically and therapeutically for conditions of the skin and mucous membranes accompanied by pain, burning, itching, and other unpleasant sensations.

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- In otorhinolaryngology: Anesthesia of the nasal mucosa (e.g., puncture of the maxillary sinus), and of the pharynx (to suppress the gag reflex when inserting instruments).
- In obstetrics: As a substitute for anesthesia in the final stage of labor and for suturing ruptures and episiotomy wounds.
- In dentistry: Anesthesia of the oral mucosa prior to injections, removal of tartar, and incision of small abscesses; anesthesia of the throat mucosa to suppress the gag reflex when taking intraoral impressions or X-rays.
- During anesthesia: To prevent coughing of the patient after intubation under superficial anesthesia, laryngoscopy, bronchoscopy, and esophagoscopy.

Xylocaine 100 mg/ml Spray is indicated for use in adults and children aged 2 years and older.

Dosage and method of administration
Dosage
Xylocaine spray is intended for application to mucous membranes. Surface anesthesia of the mucosa occurs within 1-3 minutes, depending on the area of application, and is expected to last approximately 10-15 minutes. As with all local anesthetics, the minimum effective dose should be used to minimize the risk of possible side effects. The number of sprays to be applied depends on the area to be anesthetized.

The following dosage recommendations serve as a guideline. The experience of the physician and knowledge of the patient's physical condition are important in calculating the required dosage. Each puff from the pump delivers 10 mg Xylocaine base.
It is not necessary to dry the area to be anesthetized before administration.

Xylocaine 100 mg/ml Spray should not be applied to the cuffs of endotracheal tubes (ETT) made of plastic (see also section 4.4 of the SPC).

Administration area	Recommended dosage (mg)	Maximum dosage for short[1] procedures (mg)	Maximum dosage for long-term[2] procedures (mg)
Anesthesia of the nasal mucosa	20 - 60	500	600
Oral cavity and dentistry	20 – 200	500	600
Ooropharynx (e.g. Gastrointestinal endoscopy)	20 – 200	500	600
Intubation in the airways (e.g. laryngo-, tracheo- and bronchoscopy)	50 – 400	400	600
Procedures in the larynx, trachea and bronchi	50 – 200	200[3]	400
Obstetrics and gynecology	50 – 200	400	600

1. For short procedures, the medication is given for less than a minute
2. For prolonged procedures, administered for more than 5 minutes
3. During ventilation, the dosage should be reduced

The maximum dose also varies with the site of administration as the absorption of lidocaine depends on the area of administration and is particularly higher in the trachea and bronchi (see section 5.2 of the SPC).

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Elderly
Dosages in debilitated or elderly patients should be consistent with their physical condition.

Pediatric patients

Children over 12 years
Children from 12 years who weigh less than 25 kg should be dosed according to their weight and physical condition.

Children from 2 to 12 years
The maximum dose for children should be calculated based on mg/kg body weight. When applying Xylocaine Spray in the larynx and trachea, the maximum dose is 3 mg/kg, and when applied in the nose, mouth, oropharynx, a dose of 4 – 5 mg/kg should not be exceeded.

Children under 2 years
For neonates and babies under 2 years, less concentrated lidocaine solutions are recommended.

Method of administration
See section 6.6 of the SPC for instructions for use and instructions regarding the dosing valve.

Contraindications
- Hypersensitivity to the active substance, or to any of the excipients listed in section 6.1.
- Known hypersensitivity to local anesthetics of the amide type, such as bupivacaine, mepivacaine, and prilocaine.

Special warnings and precautions for use
Patients treated with class III antiarrhythmics (e.g., amiodarone) should be closely monitored and ECG monitoring should be considered, as additive effects on the heart may occur.

High doses or short intervals between doses can lead to high plasma concentrations and potentially serious side effects. Absorption from wound surfaces and mucous membranes is relatively high, especially in the bronchial tree. Administration in these areas can therefore lead to rapidly rising or excessively high plasma concentrations, with an increased risk of toxic effects, such as seizures. Lidocaine spray should therefore be used with caution in patients with damaged mucous membranes and/or inflammation in the area where the spray is applied. Application on damaged mucous membranes leads to increased systemic absorption. In the treatment of severe side effects, resuscitation equipment, oxygen, and other life-saving drugs may be needed (see section 4.9 of the SPC). The possibility of laryngeal edema should be considered.

In patients under general anesthesia, higher plasma concentrations may occur than in patients who breathe spontaneously. Patients who are conscious swallow a larger portion of the dose, which is then subject to significant first-pass metabolism in the liver after absorption from the intestine.

The use of local anesthetics in the oropharyngeal area can affect the swallowing process and therefore increase the risk of aspiration.
Numbness of the tongue or oral mucosa can increase the risk of bite injuries. To minimize this risk, one should not eat until the anesthetic effect is diminishing.

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If the dosage used or the site of administration is likely to lead to high blood levels of lidocaine, then, as with other local anesthetics, caution should be exercised in:

- elderly patients and patients in poor general condition,
- patients in severe shock,
- epilepsy,
- patients with cardiovascular problems and heart failure,
- patients with cardiac conduction disorders (especially partial or complete AV block),
- bradycardia,
- patients with severely impaired liver function,
- patients with severely impaired renal function.

Xylocaine 100 mg/ml Spray should not be applied to the cuffs of endotracheal tubes (ETT) made of plastic. If lidocaine base comes into contact with the PVC or non-PVC of the cuffs of endotracheal tubes, it can damage the cuff. These damages are described as small holes that can cause leakage, thereby lowering the pressure in the cuff.

Xylocaine 100 mg/ml Spray should not be sprayed into the eye. If the liquid accidentally gets into an eye, the eye should be rinsed immediately with water or a 0.9% sodium chloride solution.

Xylocaine 100 mg/ml Spray may be porphyrinogenic, so before treating patients suffering from porphyria with the spray, a careful consideration must be made whether the benefits outweigh the disadvantages. All necessary precautions should be taken for porphyria patients.

Interactions with other medicinal products and other forms of interaction
Lidocaine should be used with caution in patients who are also using other local anesthetics or other agents structurally related to amide-type local anesthetics. Examples include antiarrhythmics such as mexiletine or tocainide. Since the systemic toxic effects are additive, there is a risk of overdose.

No specific interaction studies with lidocaine and class III antiarrhythmics (such as amiodarone) have been conducted, but caution should be exercised when treating patients (see also section 4.4 of the SPC).

If lidocaine is used repeatedly in high doses over a longer period, drugs that reduce the clearance of lidocaine, such as cimetidine or beta-blockers, could in principle lead to a clinically relevant increase in plasma levels. This is not expected with short-term use of Xylocaine 100 mg/ml Spray at the recommended dosage.
Factors such as acidosis and the use of CNS stimulants and depressants affect the CNS levels of lidocaine required to produce an overt systemic effect.

PHARMACEUTICAL DATA
List of excipients
Ethanol (96%)
Macrogol 400
Banana flavor (85509/H, Givaudan),
Levomenthol
Saccharin
Purified water.

Cases of incompatibility

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Not applicable.

Shelf life
Do not use this medicine after the expiry date. You will find this on the label and the box after "EXP:". It states a month and a year. The last day of that month is the expiry date. Special precautions for storage
Store below 25 °C. Cloudiness may occur if stored below 8°C, which dissolves at room temperature. Store upright.

Nature and contents of the packaging and other instructions
Xylocaine 100 mg/ml Spray: box with a glass bottle containing 50 ml of liquid for spraying (sufficient for approximately 500 sprays) including a polypropylene dosing valve approximately 12 cm long (mouthpiece) for single use. Short mouthpieces can be ordered separately.
If necessary, a box with long, sterile, disposable mouthpieces (50 pieces) can be ordered separately.

Special precautions for disposal and other instructions
The dosing valve (mouthpiece) is ready for use and no additional actions are needed to use the mouthpiece. Never cut the dosing valve, as this will destroy the spraying mechanism. Remove the plastic cap from the bottle and slide the dosing valve (mouthpiece) onto the bottle. Pressing the button on the mouthpiece dispenses a precisely measured amount of liquid containing 10 mg of lidocaine base. Mouthpieces should not be reused and must be discarded immediately after use.

MARKETING AUTHORIZATION HOLDER
Registration holder/repacker:
Eureco-Pharma B.V.
Boelewerf 2
2987 VD Ridderkerk

MARKETING AUTHORIZATION NUMBER(S)
Xylocaine 100 mg/ml Spray is registered under RVG 127178//07831.

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