PACKAGE LEAFLET

Package leaflet: Information for the user

Xylocaine 20mg/g Gel

lidocaine hydrochloride

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

What is in this leaflet

1. What Xylocaine 20mg/g Gel is and what it is used for
2. What you need to know before you use Xylocaine 20mg/g Gel
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4. Possible side effects
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1. What Xylocaine 20mg/g Gel is and what it is used for

Xylocaine 20mg/g Gel belongs to the group of agents used for local anaesthesia (local anaesthetics). It contains lidocaine, a short-acting, amide-type local anaesthetic with a rapid onset of action.

Xylocaine 20mg/g Gel is used in adults and adolescents aged 12 years and above.
- for local anaesthesia and is also used to make it easier to insert bladder catheters, gastric tubes, etc. In this case, Xylocaine 20mg/g Gel acts as an anaesthetic and lubricant.
- for examination of body cavities and internal channels (endoscopic procedures).
- for insertion of a breathing tube into the throat (intubation).

2. What you need to know before you use Xylocaine 20mg/g Gel

Do not use Xylocaine 20mg/g Gel
- if you are allergic to lidocaine hydrochloride monohydrate or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to other amide-type local anaesthetics.
- in children under 2 years of age.

Warnings and precautions
- Always let the doctor(s) treating you know what other problems or illnesses you are being treated for. This particularly applies if you are using medicines for heart rhythm disorders (see also section 'Other medicines and Xylocaine 20mg/g Gel') and if you suffer from a metabolic disease called porphyria.
- Xylocaine 20mg/g Gel must be used with caution if the mucous membranes in the area where the gel is used are damaged, or if there is inflammation in that area.
- If your throat has been numbed with Xylocaine 20mg/g Gel, you should preferably not eat or drink until the numbness has worn off. Otherwise, you may choke or bite your tongue or cheek while the oral cavity is still numb.
- Xylocaine 20mg/g Gel must also be used with caution in elderly patients, patients in a poor general condition, in severe state of shock, with epilepsy, with heart rhythm disorders, with heart failure or other cardiovascular problems, or patients with liver or kidney function disorders. This particularly applies if high dosages are required.

- Always let the doctor(s) treating you know if you or your child have a problem with blood pigment levels called “methaemoglobinaemia”.

Talk to your doctor or pharmacist or nurse before using Xylocaine 20mg/g Gel.

Other medicines and Xylocaine 20mg/g Gel
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This also applies to medicines obtained without a prescription.

- Antiarrhythmics - medicines to treat an irregular heartbeat (e.g. mexiletine, amiodarone).
- Medicines for epilepsy such as carbamazepine, phenobarbitone, phenytoin and primidone,
- Other medicines containing lidocaine or certain other local anaesthetics (of the amide type), as they may enhance their respective effects in an unpredictable manner. Your doctor may need to adjust the dose accordingly.
- Cimetidine or beta-blockers medicines such as metoprolol, nadolol and propranolol, these medicines may have an enhanced effect on the heart.
- Medicines that can affect the colouring of your blood (blood pigments), such as sulphonamides, nitrofurantoin, phenytoin, or phenobarbital. These medicines may increase the risk of a blood problem called methaemoglobinaemia.

Xylocaine 20mg/g Gel with food and drink
If your throat has been numbed with Xylocaine 20mg/g Gel, you should preferably not eat or drink until the numbness has worn off. Otherwise, you may choke or bite your tongue or cheek while the oral cavity is still numb.

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 or pharmacist for advice before using this medicine.

You can be treated with Xylocaine 20mg/g Gel during pregnancy and breast-feeding. During pregnancy and breast-feeding, Xylocaine 20mg/g Gel should only be used after your doctor has carefully considered the benefits and risks.

Driving and using machines
Use of Xylocaine 20mg/g Gel can temporarily affect reaction skills in some cases. Please take this into account if driving.

Xylocaine 20mg/g Gel contains methyl p-hydroxybenzoate (E 218) and propyl p-hydroxybenzoate (E 216)
May cause allergic reactions (possibly delayed).

3. How to use Xylocaine 20mg/g Gel

One gram (g) of gel is equivalent to one millilitre (ml) of gel.
Xylocaine 20mg/g Gel will often be applied by the doctor. However, in some cases, you can apply the gel yourself. In this case, always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults
Before using the Xylocaine 20mg/g Gel in the urethra, the opening of the urethra and glans must be carefully cleaned.
The recommended dose is:
For bladder procedures in women 5-10 grams of gel and in men 10-20 grams of gel each time; in men up to 40 grams of gel can be safely given in a in a 24 hour period.
To anaesthetise only the anterior male urethra e.g. for catheterisation (including self-catheterisation), small amounts (5-10 g of gel) are usually adequate.

For endoscopy 10-20 grams of gel;
For intubation, apply approximately 2 grams of gel to the tube surface.
For rectoscopy up to 20 grams of gel.

If you are an adult in poor condition or elderly, your doctor will adjust the dosage.

Use in children and adolescents
Children < 2 years of age
Xylocaine 20mg/g Gel must not be used in children < 2 years of age.

Children (below 12 years)
Not for use in children below 12 years.

Adolescents (aged 12 years and above)
The doctor will determine the dose depending on the adolescent's age, weight and physical condition.

Numbness usually starts within 5 minutes of applying the gel and lasts about 20 to 30 minutes.

If you use more Xylocaine 20mg/g Gel than you should
Signs
As a rule, signs will only occur after using very large amounts of Xylocaine 20mg/g Gel. The first signs of overdose are yawning, restlessness, dizziness, nausea, vomiting, slurred speech, hearing and/or vision disorders, tremors and impaired balance or movement coordination. Muscle twitching and seizures, possibly followed by loss of consciousness and coma, may be symptoms of a more serious overdose.
Symptoms affecting cardiovascular system may include slower than normal heart rate, irregular heartbeat and low blood pressure.

Signs of central nervous system toxic symptoms generally precede toxic cardiovascular effects unless the patient is under general anaesthesia or deeply sedated with drugs such as benzodiazepines or barbiturates.

What must you do?
Tell a doctor immediately. Try to find out how much Xylocaine 20mg/g Gel has been used or swallowed. Keep the pack of Xylocaine 20mg/g Gel at hand.

If you forget to use Xylocaine 20mg/g Gel
Xylocaine 20mg/g Gel is usually applied in the operating theatre or treatment room at outpatient clinics. It is unlikely that anyone will forget to apply your dose of Xylocaine 20mg/g Gel. Check with your doctor if you are not sure.
If you apply Xylocaine 20mg/g Gel yourself and you have forgotten to use it, you can still apply the gel.

If you stop using Xylocaine 20mg/g Gel
Never reduce the dosage yourself or (temporarily) stop treatment without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been reported.

Sore throat may occur after surgery when Xylocaine 20mg/g Gel is used while inserting a breathing tube into the throat.

Rare (in less than 1 in 1 000 patients)

Hypersensitivity reactions, shock (sharp drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin, reduced consciousness) due to sudden, severe vasodilation as a result of severe hypersensitivity to certain substances (anaphylactic shock).

Symptoms of overdose when more active substance than usual is absorbed into the body.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xylocaine 20mg/g Gel

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

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

Store below 25°C. Do not refrigerate or freeze. Keep the tube in its unopened blister until use.

The tubes are intended for single use only. Any unused gel and nozzle applicator should be discarded after first opening.

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 Xylocaine 20mg/g Gel contains

- The active substance is lidocaine hydrochloride monohydrate, equivalent to 20mg/g lidocaine hydrochloride anhydrous.
- The other ingredients are hypromellose (E 464), methyl p-hydroxybenzoate (E 218), propyl p-hydroxybenzoate (E 216), hydrochloric acid (E 507) (for pH adjustment), sodium hydroxide (E 524) (for pH adjustment) and water for injection.

What Xylocaine 20mg/g Gel looks like and contents of the pack

Xylocaine 20mg/g Gel is a clear to almost clear, light-coloured sterile gel.
Xylocaine 20mg/g Gel is available in a 30 g aluminium tube with applicator device. The tubes are individually packed in a sterile transparent blister pack.
Each pack contains a CE certified medical device.

Pack Sizes
1 x 30 g tube

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland
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Manufacturer:
Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

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