

**XYLOCAINE 2%, urethral gel in pre-filled syringe**  
**Lidocaine hydrochloride**

**Framed**

**Read all of this leaflet carefully before using this medicine because it contains important information for you.**

- Keep this leaflet. You might need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed. Do not give this to anyone else. 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 pharmacist. This also applies to any side effects that are not mentioned in this leaflet. See section 4.

**What does this booklet contain ?**

1. What is XYLOCAINE 2%, urethral gel in pre-filled syringe and in which cases is it used?
2. What should I know before using XYLOCAINE 2% urethral gel in a pre-filled syringe?
3. How to use XYLOCAINE 2%, urethral gel in a pre-filled syringe?
4. What are the possible side effects?
5. How to store XYLOCAINE 2%, urethral gel in a pre-filled syringe?
6. Contents of the pack and other information.

**1. WHAT IS XYLOCAINE 2%, urethral gel in pre-filled syringe AND WHAT IT IS USED FOR?**

Pharmacotherapeutic group: LOCAL ANESTHESICS (N: Central Nervous System), ATC code: N01BB02.

XYLOCAINE 2% belongs to the group of local anesthetics with an amide bond.

This medication is indicated in adults and children of all ages during local anesthesia before exploration of the urinary tract.

**2. WHAT YOU NEED TO KNOW BEFORE you use XYLOCAINE 2%, urethral gel in a pre-filled syringe?**

**Never use XYLOCAINE 2%, urethral gel in a pre-filled syringe:**

- Allergy to local anesthetics amide bond,
- Recurrent porphyria (genetic diseases, hereditary reaching the production of hemoglobin),
- Uncontrolled epilepsy treatment.

In case of doubt, it is essential to seek the advice of your doctor or pharmacist.

## **Warnings and Precautions**

### **Special warning**

Do not inject. Do not swallow.

In patients with cardiac arrhythmias treated with antiarrhythmic drugs, due to the addition of cardiac effects, close monitoring is necessary.

### **Precaution for use**

Particular monitoring is necessary in the event of use on a traumatized or inflammatory urethral mucosa because of the risk of causing a more or less important passage of a part of the active principle in the blood. In this case, a reduction in the doses used is recommended.

Talk to your doctor or pharmacist before using XYLOCAINE 2%, urethral gel in a pre-filled syringe .

### **Other medicines and XYLOCAINE 2%, urethral gel in pre-filled syringe**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, including medicines without a prescription.

### **XYLOCAINE 2%, urethral gel in pre-filled syringe with food and drink**

Not applicable.

### **Pregnancy and breast feeding**

This medication can be used during pregnancy regardless of the term.

Breastfeeding is possible after local anesthesia.

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 taking this medicine.

### **Sportsmen**

The attention of athletes is drawn to the fact that this specialty contains an active principle which can induce a positive reaction to the tests carried out during doping controls.

### **Driving and using machines**

This product may affect the reaction capabilities when driving vehicles or using machines. It is recommended that you do not drive for hours after using this medication.

### **XYLOCAINE 2%, urethral gel in pre-filled syringe contains**

Not applicable.

## **3. HOW TO use XYLOCAINE 2%, urethral gel in a pre-filled syringe?**

### **Dosage**

The maximum quantity available is 10 g.

As with any urethral anesthesia, it is recommended to use XYLOCAINE 2%, gel from the first maneuver, in order to avoid too much blood flow of the anesthetic through a mucous membrane scuffed by unsuccessful attempts.

After careful disinfection of the urinary meatus with a mild antiseptic, gently introduce the end of the syringe into the meatus until it is sealed, after following the instructions for handling the syringe (see paragraph "Method and route of administration").

### In humans

Slowly inject the contents of the syringe, without forcing, by simply pressing the plunger.  
Place a rod forceps for 3 minutes at the level of the balano-preputial groove. The anesthesia is complete after 5 to 10 minutes.

### In women

Slowly inject a few grams of gel into the urethra by simply pressing the plunger of the syringe.

### In children

The amount of gel administered will be adapted to the weight of the child and the growth of the urethral canal. The dosage is 2 to 4 mg / kg of lidocaine hydrochloride, i.e. a gel dose of 0.1 to 0.2 g / kg of weight.

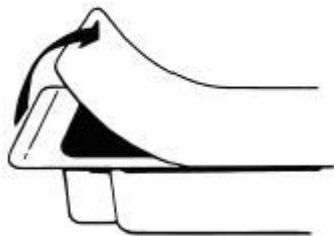
### **Method and route of administration**

Local urethral route.

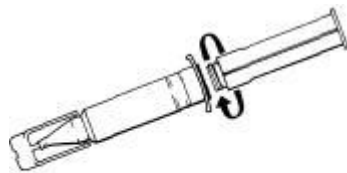
The pre-filled syringe is for single use; after first use, all unused product should be discarded.

It is recommended to use this medication from the first maneuver, in order to avoid too much blood flow of lidocaine through an injured mucosa.

1- Remove the pre-filled syringe from the sterile tray to check its integrity.



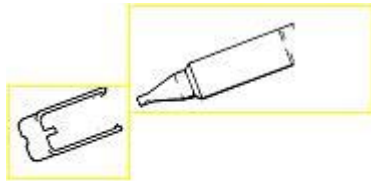
2- Assemble the two parts of the syringe by screwing the plunger on the seal at the end of the syringe body.



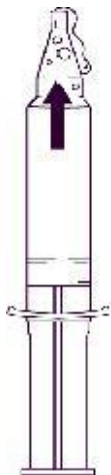
3- Remove the tip of the syringe by rotating the upper part in the direction indicated by the arrow.



4- Inspect the syringe to ensure that there is no plastic fragment in the gel.  
Check that the sealing tip has been completely removed.



5- Hold the syringe vertically and lower all the gel into the lower part by tapping on the end, then purge the air before injecting the gel.



6- Slowly inject the gel.

7- Clamp if necessary to prevent the product from spilling out.

**If you use more XYLOCAINE 2%, urethral gel in a pre-filled syringe than you should**

In the event of accidental massive administration, notify your doctor immediately.

Treatment of a patient showing signs of systemic toxicity involves stopping the seizures and ensuring adequate ventilation with oxygen, if necessary by assisted or controlled ventilation (breathing). In adults, when seizures occur, they should be treated promptly by intravenous injection of short-acting barbiturates or benzodiazepines. Intravenous succinylcholine (50-100 mg) can be used to provide muscle relaxation provided the clinician is able to perform endotracheal intubation and manage a completely paralyzed patient.

After the seizure has stopped and adequate pulmonary ventilation is provided, no further treatment is usually necessary. However, in the event of hypotension, or bradycardia, 5 to 10 mg of ephedrine will be injected intravenously and repeated if necessary after 2 to 3 minutes.

**If you forget to use XYLOCAINE 2%, urethral gel in a pre-filled syringe**

Not applicable.

**If you stop using XYLOCAINE 2%, urethral gel in pre-filled syringe**

Not applicable.

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

**4. WHAT ARE THE POSSIBLE SIDE EFFECTS?**

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

The occurrence of an adverse reaction should raise suspicion of an overdose. Toxic neurological or cardiovascular reactions, indicating an abnormally high concentration of anesthetic in the blood, may appear after the use of too much anesthetic or in the event of particular susceptibility.

- Cardiac disorders: increased heart rate, rhythm disorders, disorders of conduction or cardiovascular depression, up to collapse or cardiac arrest.
- Vascular disorders: increase or decrease in blood pressure.
- Nervous system disorders: yawning, headaches, tremors, convulsions
- Psychiatric disorders: nervousness, agitation, anxiety, verbal diarrhea,
- Ear and labyrinth hissing, ringing,
- Eye disorders involuntary eye movements
- Muscle disorders: involuntary muscle contractions,
- Skin and mucous membranes: rash, itching
- Immune system: hives, swelling, respiratory discomfort, anaphylactic shock,
- Respiratory: increased respiratory rate and breathing difficulty
- Gastrointestinal disorders nausea.

**Reporting of side effects**

If you get any side effects talk to your doctor or pharmacist. This also applies to any side effects that are not mentioned in this leaflet. You can also report side effects directly via the national reporting system: National Agency for the Safety of Medicines and Health Products (ANSM) and network of Regional Pharmacovigilance Centers - Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

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

**5. HOW TO STORE XYLOCAINE 2%, urethral gel in a pre-filled syringe?**

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

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

Do not store above 25 ° C.

Do not freeze.

Do not throw away any medicine 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 PACKAGE AND OTHER INFORMATION**

### **What XYLOCAINE 2% contains, urethral gel in pre-filled syringe**

- The active substance is:

Lidocaine hydrochloride monohydrate ..... 2.132 g  
Corresponding amount of anhydrous lidocaine hydrochloride ..... 2,000 g  
Per 100 g of urethral gel.

- The other ingredients are: hypromellose, sodium hydroxide and / or hydrochloric acid, water for injections.

### **What is XYLOCAINE 2%, urethral gel in pre-filled syringe and contents of the pack**

This medication is in the form of urethral gel in a pre-filled syringe; box of 1 and 10 in sterile tray.

### **Marketing authorization holder**

#### **ASPEN PHARMA TRADING LIMITED**

3016 LAKE DRIVE  
CITYWEST BUSINESS CAMPUS  
DUBLIN 24  
IRELAND

### **Marketing authorization operator**

#### **ASPEN FRANCE**

21 AVENUE EDOUARD BELIN  
92500 RUEIL MALMAISON

### **Maker**

#### **RECIPHARM MONTS**

18 RUE DE MONTBAZON  
37260 MONTS  
OR

#### **ASTRAZENECA AB**

ASTRAALLEN, GÄRTUNAPORTEN (B 674: 5)

151 85 SÖDERTÄLJE

SWEDEN

OR

**RECIPHARM KARLSKOGA AB**

BJÖRKBORNSVÄGEN 5

691 33 KARLSKOGA

SWEDEN