

# INSTILLAGEL LIDO

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using INSTILLAGEL LIDO?

INSTILLAGEL LIDO contains the active ingredient lidocaine hydrochloride(as monohydrate). INSTILLAGEL LIDO is used for local anaesthesia.

For more information, see Section [1. Why am I using INSTILLAGEL LIDO?](#) in the full CMI.

### 2. What should I know before I use INSTILLAGEL LIDO?

Do not use if you have ever had an allergic reaction to lidocaine hydrochloride or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use INSTILLAGEL LIDO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with INSTILLAGEL LIDO and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use INSTILLAGEL LIDO?

- INSTILLAGEL LIDO is a sterile gel available in 6mL and 11mL pre filled syringes.

More instructions can be found in Section [4. How do I use INSTILLAGEL LIDO?](#) in the full CMI.

### 5. What should I know while using INSTILLAGEL LIDO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using INSTILLAGEL LIDO.</li><li>• Use INSTILLAGEL LIDO as instructed by your doctor.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use more of this medicine than instructed by your doctor.</li><li>• Do not use if you are allergic to any of the ingredients or to local anaesthetics</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store INSTILLAGEL LIDO at room temperature (below 25°C) away from direct heat, Do not refrigerate or freeze.</li><li>• INSTILLAGEL LIDO is for single use only. Use immediately after opening the blister.</li></ul> <p>The syringe and any gel not used in a single application must be discarded.</p>

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) in the full CMI.

### 6. Are there any side effects?

Some side effects that may occur include allergic reaction which may result in swelling of hands, feet, face, lips, mouth , tongue or throat, difficulties in breathing, skin rash or hives or a drop in blood pressure and shock. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# INSTILLAGEL LIDO

**Active ingredient(s):** Lidocaine hydrochloride (as monohydrate) 2% w/w

## Consumer Medicine Information (CMI)

This leaflet provides important information about using INSTILLAGEL LIDO. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INSTILLAGEL LIDO.**

**Where to find information in this leaflet:**

- [1. Why am I using INSTILLAGEL LIDO?](#)
- [2. What should I know before I use INSTILLAGEL LIDO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use INSTILLAGEL LIDO?](#)
- [5. What should I know while using INSTILLAGEL LIDO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using INSTILLAGEL LIDO

INSTILLAGEL LIDO contains the active ingredient **lidocaine hydrochloride(as monohydrate) 2%w/w** which has a local anaesthetic effect and is used to numb the parts of the body the gel is applied to. It stops the nerves from being able to pass pain messages to the brain and so stops you feeling pain.

**INSTILLAGEL LIDO is used** to relieve discomfort and ease the process during certain types of examinations or procedures.

- for instillation (insertion) into the urethra before a catheter is inserted or replaced and for a cystoscopy, when a doctor inserts a tube through the urethra to visualise your bladder.
- for proctoscopy/rectoscopy (medical procedures in which an instrument called an endoscope is used to examine the anal cavity or rectum). During this procedure, INSTILLAGEL LIDO is instilled into the anal cavity/rectum and/or the instrument used is lubricated with INSTILLAGEL LIDO before insertion

## 2. What should I know before I use INSTILLAGEL LIDO?

### Warnings

**Do not use INSTILLAGEL LIDO if:**

- you are allergic to lidocaine hydrochloride or any of the ingredients listed at the end of this leaflet.

- if you are allergic to certain other local anaesthetics (of the amide type).
- in children below 2 years of age.
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- if you have any wounds, injury to the mucous membranes or an ulcer/inflammation in or around the proposed application site.
- if your liver or kidney function is impaired, if you are acutely ill, in a weak condition or have sepsis ("blood poisoning"). Your doctor may reduce your dose of Instillagel Lido
- if you have a slow heartbeat, a heart or respiratory tract dysfunction (problems with your airways).
- if you have a weak heart (heart failure) or heart conduction disturbances (atrioventricular block).
- if you suffer from a medical shock.
- if you are prone to convulsions (seizures) or if you have epilepsy.
- if you are suffering from a certain muscle disease (myasthenia gravis).
- if you have a rare inherited illness that affects the blood called "glucose-6-phosphate dehydrogenase deficiency".
- if you have a problem with blood pigment levels called "methaemoglobinaemia".
- if you suffer from porphyria (a blood formation disorder).
- if you are on treatment with certain medications to treat heart rhythm disorders, known as class III antiarrhythmics (e.g. amiodarone), as the effects on the heart may be increased. See also **section 3.**

### What if I am taking other medicines

Please also notify your doctor if you use other medicines containing lidocaine hydrochloride frequently and/or at high doses, as this may lead to serious side effects.

If a lot of INSTILLAGEL LIDO is instilled into the urethra and a large amount of gel gets into the bladder or if the urethra is ulcerous/inflamed, this may generally lead to increased absorption of lidocaine hydrochloride through the mucous membranes, particularly in children and elderly patients, resulting in serious side effects (see also section **If you use too much INSTILLAGEL LIDO**).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

During pregnancy and breast-feeding INSTILLAGEL LIDO should only be used after your doctor has carefully considered the benefits and risks.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you are taking/using any of the following:

- **antiarrhythmics** - medicines to treat irregular heart beat (e.g. mexiletine, amiodarone).
- **calcium channel blockers** - medicines taken for heart conditions or high blood pressure (e.g. diltiazem, verapamil).
- **beta-blockers** (e.g. propranolol, metoprolol) - for the treatment of high blood pressure or angina (chest pain).  
These medicines may have an enhanced effect on the heart.
- other medicines containing **lidocaine hydrochloride** or certain other **local anaesthetics** (of the amide type), as this may enhance their respective effects in an unpredictable manner.
- **cimetidine** to treat hyperacidity, stomach and duodenal ulcers. Using this medicine at the same time can increase the risk of side effects.
- **fluvoxamine** to treat depression.
- **erythromycin** (antibiotic).
- protease inhibitors used to treat HIV (e.g. **ritonavir**).
- medicines used to treat infections, called **sulphonamides** and **nitrofurantoin**.
- medicines used to treat epilepsy, called **phenytoin** and **phenobarbital**.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect [medicine name].**

### 4. How do I use INSTILLAGEL LIDO

The administration will usually be performed by a doctor with appropriate training and relevant experience.

If you are treating yourself, such as for self-catheterisation (inserting a small plastic tube (catheter) into one's own urethra), always use this medicine exactly as your doctor has told you and follow the instructions below for how to apply the gel. Check with your doctor if you are not sure.

INSTILLAGEL LIDO starts to work within 5 - 15 minutes after the application. The effect usually lasts 20 to 30 minutes.

#### How much to use

Your doctor will decide on the most suitable dosage for your particular case according to your age and medical condition as well as for the site of application, the method used and your response.

The recommended dose is:

##### Adults

#### **For instillation (insertion) into the urethra**

##### *Male patients*

For adequate pain relief, 20 mL gel is usually required.

When anaesthesia is especially important, e.g., during sounding or cystoscopy, your doctor may instill a larger quantity of gel (up to 40 mL).

If you are treating yourself, such as for self-catheterisation, your doctor will tell you how much to use. Ask if you are not sure.

##### *Female patients*

The doctor will adapt the amount of gel to be inserted to the individual anatomical conditions of the urethra. Usually 5-10 mL of gel are instilled in small portions to fill the whole urethra.

#### **For pain relief from inflammation of the urinary bladder**

The doctor decides on the most suitable dose, frequency and duration based on your condition and symptoms.

#### **Proctoscopy/rectoscopy**

For adequate pain relief, your doctor will usually instill 10-20 mL gel into the anal cavity/rectum and will apply a small amount to lubricate the endoscope.

##### *Special population*

Your doctor may decide to reduce the dose if you are elderly, acutely ill, in a weak condition, if you have liver or kidney problems or if you have sepsis ("blood poisoning").

#### **Use in children and adolescents**

##### *Children < 2 years of age*

INSTILLAGEL LIDO must not be used in children below 2 years of age.

##### *Children (2 - 12 years) and adolescents (above 12 years of age)*

The doctor will determine the dose depending on the child's age, weight and physical condition.

## When to use INSTILLAGEL LIDO

The administration will usually be performed by a doctor with appropriate training and relevant experience.

If you are treating yourself, such as for self-catheterisation (inserting a small plastic tube (catheter) into one's own urethra), always use this medicine exactly as your doctor has told you and follow the instructions below for how to apply the gel. Check with your doctor if you are not sure.

For examinations/procedures INSTILLAGEL LIDO is usually only used for one or two doses or for a short course of treatment.

If you have been prescribed INSTILLAGEL LIDO for self-administration, your doctor will decide how long you should continue to use this medicine depending on your condition.

## How to administer INSTILLAGEL LIDO

The pre-filled graduated syringes are available with 6 mL or 11 mL gel. Your doctor will choose the appropriate size depending on the amount you need.

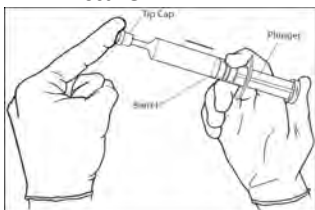
Each graduation on the syringe is equivalent to approximately 1 mL of gel (20.1 mg lidocaine hydrochloride)

### For (self-)catheterisation (urethral use)

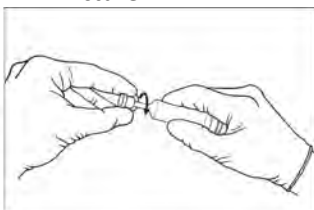
Follow these directions carefully:

1. Wash your hands. Clean and disinfect the genital area.
2. When ready to use, open the blister.
3. Before removing the tip cap from the end of the syringe, press in the plunger to remove any resistance that may be present. This helps ensure that the syringe will empty easily and uniformly. [Picture 1]
4. Remove the tip cap from the syringe. The syringe is now ready for use. [Picture 2]
5. Insert the nozzle into the opening of the urethra and press the plunger slowly and evenly to push out the gel into the urethra. [Picture 3]
6. Wait for a few minutes after instillation of the gel for the anaesthetic to take full effect. Full anaesthetic effect will occur within 5 to 15 minutes after complete instillation.

Picture 1:

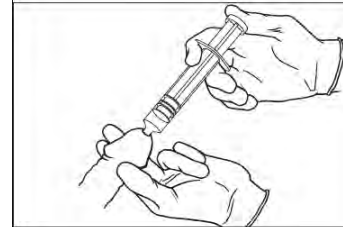
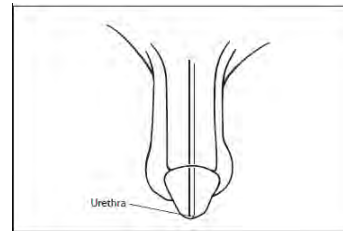


Picture 2:

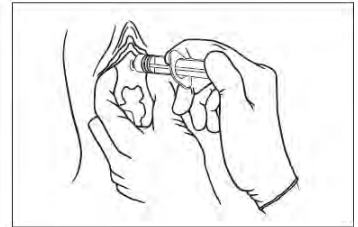
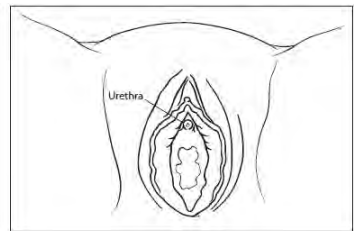


Picture 3:

Male patient:



Female patient:



### For cystoscopy

Your doctor will administer this medicine in the urethra and/or apply it to the endoscope.

### For proctoscopy/rectoscopy

Your doctor will administer this medicine in the anal cavity/rectum and/or apply it to the endoscope.

**The syringe is for single use only.** Use immediately after opening the blister.

The syringe and any gel not used in a single application must be discarded.

## If you use too much INSTILLAGEL LIDO

### Administration of INSTILLAGEL LIDO by a doctor

Since this medicine is usually administered to you by a trained doctor, it is unlikely that you will be given too much of INSTILLAGEL LIDO. Nevertheless, if you think you have been given too much medicine or you begin to experience the overdose symptoms listed below, you must tell the person giving you INSTILLAGEL LIDO immediately. Your doctor will know how to manage these symptoms and give you any necessary treatment.

### Administration of INSTILLAGEL LIDO by yourself or a caregiver for self-catheterisation

Whether you develop symptoms of an overdose or not depends on the level of this medicine present in your blood. The more lidocaine hydrochloride is in your blood, the more severely you might experience symptoms of an overdose. Normally only small amounts of the active ingredient lidocaine hydrochloride are absorbed into the blood INSTILLAGEL LIDO. Too much lidocaine hydrochloride can be absorbed if the surface being treated is damaged.

The first symptoms of overdose are for example:

problems with hearing, seeing, speaking and/or coordination of movements, yawning, restlessness, dizziness, nausea and vomiting.

If you think that you have used too much INSTILLAGEL LIDO you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using INSTILLAGEL LIDO?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using INSTILLAGEL LIDO

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how INSTILLAGEL LIDO affects you.**

Effects on the ability to drive and use machines are unlikely, but cannot be completely ruled out in cases of increased individual sensitivity. If you feel drowsy, dizzy or if you have vision disturbances, do not drive or use any tools or machinery.

### Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

### When to discard your medicine (as relevant)

INSTILLAGEL LIDO syringes are intended for single use. The syringe and any gel not used in a single application must be discarded.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

Lidocaine hydrochloride is generally well tolerated provided the medicine is used as directed. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
Administration Site - irritation	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Allergic reaction- symptoms may include:-</b> - swelling of the hands, feet, face, lips, mouth, tongue or throat - difficulties in breathing - shortness of breath due to narrowing of the airways (bronchospasm) - skin problems such as itchy skin or rash - hives - drop in blood pressure and shock	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is available only from a pharmacist.

### What INSTILLAGEL LIDO contains

<b>Active ingredient (main ingredient)</b>	• Lidocaine hydrochloride (as monohydrate)
<b>Other ingredients</b>	• Hypromellose

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"><li>• Sodium hydroxide</li><li>• Purified water</li></ul>
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**Do not use this medicine if you are allergic to any of these ingredients.**

### **What INSTILLAGEL LIDO looks like**

INSTILLAGEL LIDO is a nearly colourless, clear sterile gel. INSTILLAGEL LIDO is available as a gel in 6mL and 11mL (AUST R 468186) polypropylene disposable plastic syringes in packs of 10 pre-filled syringes per carton.

Each graduation on the syringe is equivalent to approximately 1 mL of gel (20.1 mg lidocaine hydrochloride).

An applicator nozzle is available for separate purchase.

### **Who distributes INSTILLAGEL LIDO**

InterPharma Pty Ltd  
Suite 103, 39 East Esplanade  
MANLY NSW 2095 AUSTRALIA  
Ph.: 029976 6876

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