

PACKAGE LEAFLET: INFORMATION FOR THE USER

Instillagel 6 ml/ 11ml **urethral, vaginal, rectal and oropharyngeal gel**

Lidocaine hydrochloride, chlorhexidine digluconate, methyl parahydroxybenzoate, propyl parahydroxybenzoate.

sterile

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.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

What is in this leaflet

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

1. WHAT INSTILLAGEL IS AND WHAT IT IS USED FOR

Instillagel is a gel that is used to numb the parts of the body it is applied to (local anaesthetic). It is used when examining or putting an instrument into a body cavity, such as the mouth, bladder or vagina. It provides lubrication to ease this process.

The gel contains substances (antiseptics) to reduce the risk of infection.

Instillagel may be used before you have a catheter inserted or replaced. It may also be used in your throat, bladder, vagina, rectum or colon. This makes it easier for your doctor to look inside these parts of your body without causing you discomfort.

2. WHAT YOU NEED TO KNOW BEFORE INSTILLAGEL IS USED

Do NOT use Instillagel

- if you are allergic (hypersensitive) to lidocaine, chlorhexidine, methyl parahydroxybenzoate, propyl parahydroxybenzoate, parabens or any of the other ingredients of **Instillagel** (see section 6 for details)
- if you ever had a reaction to a local anaesthetic

- **Instillagel** must not be used in children under 2 years.

Tell the person who is going to use the gel if any of these apply to you.

Warnings and precautions

Tell the person who is going to give you **Instillagel**

- if you have damaged skin
- if the moist lining (mucous membrane) of the application site (mouth, bladder, vagina, colon or rectum) is damaged
- if you have heart problems
- if you have liver problems (hepatic insufficiency, liver failure, cirrhosis)
- if you suffer from epilepsy
- if your urethra is damaged

When used in the mouth or throat, **Instillagel** may cause difficulty with swallowing because of its numbing effect. Numbness of the tongue and lining of the cheeks may increase the chance of you accidentally biting them.

Other medicines and Instillagel

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell the person who is going to give you **Instillagel** if you are taking any medicines for treating irregular heartbeats.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Tell the person who is going to give you **Instillagel** if you are pregnant or think you might be pregnant.

You should only have **Instillagel** applied if absolutely necessary during the first three months of pregnancy.

It is not known if **Instillagel** passes into breast milk. Therefore, you should not breastfeed until 12 hours after you have been given **Instillagel**.

Driving and using machines

You may feel drowsy after you have been given **Instillagel**. In this case, do not drive or use machinery.

Instillagel contains Parahydroxybenzoates and their esters

Instillagel contains Methyl Parahydroxybenzoate and Propyl Parahydroxybenzoate which may cause allergic reactions (possibly delayed).

Instillagel contains Propylene Glycol

Instillagel contains 3.14 g Propylene Glycol in each syringe of 6 ml and 5.75 g Propylene Glycol in each syringe of 11 ml. This is equivalent to 522.5 mg/ml.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Propylene Glycol may cause skin irritations.

3. HOW TO USE INSTILLAGEL

A doctor or nurse will apply the necessary amount of **Instillagel** where it is needed.

a) For urethral probe examination and catheterization:

Instill 6 or 11 ml. After the normal cleaning of the glans and the external urethral orifice, instill **Instillagel** slowly into the urethra, keeping the glans compressed, until the local anaesthetic and disinfectant action has set in.

b) For cystoscopy:

Instill 11 ml, and possibly an additional 6 or 11 ml. The entire urethra including the external sphincter must be covered with the lubricating film and anaesthetized for germ-free and painless introduction of instruments. A penis clamp is attached in the region of the sulcus coronarius.

In women, children (2-12 years) and adolescents (under 18 years) the effect of **Instillagel** with lidocaine is not so well demonstrated and therefore the need to use it should be assessed by the doctor. Specific dosage recommendations cannot be given for these groups of patients, but as a general rule, the amount of gel instilled is adapted to the individual anatomical conditions of the urethra.

The systemic absorption of lidocaine can be increased in children and caution is accordingly required. In general, the maximum dose in children aged 2 to 12 years of 2.9 mg/kg lidocaine hydrochloride should not be exceeded.

The anaesthetic takes about 5 to 10 minutes to work after the gel has been applied.

If more Instillagel is used than it should

In the unlikely event you are given more **Instillagel** than you should, you may experience the following:

- fits (convulsions)
- difficulty breathing
- your heart stopping beating (cardiac arrest)

Inform your doctor immediately if you notice any of these symptoms. If you have any further questions on the use of this product, ask your doctor.

4. POSSIBLE SIDE EFFECTS

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

Use of the gel should be stopped and you should **seek immediate medical help** if you get a **rash, swelling of the area the gel has been applied to**, or you have **difficulty breathing**. These effects may be the symptoms of a severe allergic reaction, which is very rare (occurs in fewer than one person in 10,000).

Reporting of side effects

If you get any side effects, talk to your doctor, 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 INSTILLAGEL

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 package and the syringe label after "EXP". The expiry date refers to the last day of that month.

Do not store above 25 °C.

Each syringe is for single use only. Any unused gel remaining in the syringe should be disposed of.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Instillagel contains

- The active substances are:
Lidocaine hydrochloride, chlorhexidine digluconate, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216)

6 ml of **Instillagel** gel contain:

125.40 mg Lidocaine Hydrochloride
3.14 mg Chlorhexidine Digluconate
3.76 mg Methyl Parahydroxybenzoate (E218)
1.57 mg Propyl Parahydroxybenzoate (E216)

11 ml of **Instillagel** gel contain:

230.00 mg Lidocaine Hydrochloride
5.75 mg Chlorhexidine Digluconate
6.90 mg Methyl Parahydroxybenzoate (E218)
2.87 mg Propyl Parahydroxybenzoate (E216)

- The other ingredients are:

Hydroxyethylcellulose, Propylene Glycol (E1520) *, Sodium Hydroxide and Purified Water.

*May cause skin irritations.

What Instillagel looks like and contents of the pack

Instillagel is a clear, almost colourless, slight opalescent, viscous gel.

It comes in 6 ml or 11 ml pre-filled syringes with a rubber stopper. They are packed in boxes, each containing 10 syringes.

Marketing Authorisation Holder

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Practical tip!

Before removing the blue sealing cap, press in the plunger to release the pressure point. This ensures that the syringe will empty easily and uniformly.

