

Patient Information Leaflet

Active substances

Lidocaine Hydrochloride, Chlorhexidine Digluconate, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate.

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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Your medicine is called Instillagel and will be referred to as Instillagel throughout this leaflet.

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 **Instillagel** is used
- 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. These are Chlorhexidine Gluconate, Methyl Hydroxybenzoate and Propyl Hydroxybenzoate.

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

This medicine is suitable for most people but a few should not use it. If you are in any doubt, talk to your doctor.

Do NOT use Instillagel:

- if you are allergic (hypersensitive) to Lidocaine, Chlorhexidine, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate or any of the other ingredients of **Instillagel** (see Section 6 for details).
- if the moist lining (mucous membrane) of the application site (mouth, bladder, urethra, vagina, colon or rectum) is damaged or bleeding.

Warnings and precautions

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

- if you have heart problems (cardiac insufficiency, heart failure)
- if you have liver problems (hepatic insufficiency, liver failure, cirrhosis)
- if you suffer from epilepsy

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

Tell your doctor if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription. Tell your doctor if you are taking drugs for irregular heartbeat (antiarrhythmic drugs).

Instillagel with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy and breast-feeding

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

If you are pregnant, think you may be pregnant or are planning to have a baby, ask the person who is going to give you **Instillagel** for advice.

You should only have **Instillagel** applied if absolutely necessary during the first three months of pregnancy. As only very small amounts of lidocaine get into breast milk, you can continue to breast feed.

Driving and using machines

You may feel drowsy after using **Instillagel**. If so, do not drive or use machinery.

Instillagel contains:

- Methyl Hydroxybenzoate and Propyl Hydroxybenzoate, which may cause allergic reactions (possible delayed).
- Propylene Glycol 3.14 g 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. Propylenglycol may cause skin irritation.

3 How Instillagel is used

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

Male adult urethra: Instil 11ml, and possibly an additional 11ml.

Female adult urethra: Instil 6ml to 11ml.

If you use more Instillagel than you should:

Normally only small amounts of the active ingredient lidocaine are absorbed into the blood from **Instillagel**. Too much lidocaine can be absorbed if the surface being treated is damaged. In these cases you may experience:

- fits (convulsions)
- unconsciousness
- stop breathing (respiratory arrest)

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- low blood pressure (hypotension)
- changes in your heart rate or rhythm (myocardial depression, bradycardia)
- your heart stopping beating (cardiac arrest).

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. Possible side effects include:

- serious allergic reaction that might cause difficulty with breathing or dizziness (anaphylaxis).
- low blood pressure (hypotension)
- changes in heart rate (bradycardia)
- fits (convulsions).

It is not known how frequently these side effects occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

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 store above 25°C.
- The syringe is for single use only. Discard the syringe and any unused gel after use.

Do not use Instillagel after the expiry date shown on the packaging.

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.

If your medicine becomes discoloured or shows any signs of deterioration consult your pharmacist who will advise you what to do.

6 Contents of the pack and other information

What Instillagel contains

Composition: 100g gel contains the active ingredients:

Lidocaine Hydrochloride 2.000g,
Chlorhexidine Gluconate Solution 0.250g,
Methyl Hydroxybenzoate (E218) 0.060g
Propyl Hydroxybenzoate (E216) 0.025g

The gel contains the following inactive ingredients: Hydroxyethylcellulose, Propylene Glycol and Purified Water.

Warning - Methyl Hydroxybenzoate and Propyl Hydroxybenzoate may cause allergic reactions (possibly delayed) and exceptionally, bronchospasm.

Warning - Propylene Glycol may cause skin irritation.

One of the active ingredients in this medicine is Lidocaine Hydrochloride. This is the new name for Lignocaine Hydrochloride. The ingredient itself has not changed.

What Instillagel looks like and contents of the pack

Instillagel is available in packs of 1 or 10 individually blister sealed sterile disposable polypropylene syringes containing either 6ml or 11ml of gel.

Who manufactured your medicine?

The gel is manufactured by Farco-Pharma GmbH, Gereonsmuhlegasse 1-11, Cologne D-50670, Germany and procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

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