

Instillagel

sterile

Active substances:

Lidocaine Hydrochloride, Chlorhexidine Gluconate, 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.



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. Propylene Glycol 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 11 ml, and possibly an additional 6 ml to 11 ml.

Female adult urethra: Instil 6 ml to 11 ml.

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)
- 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, pharmacist or nurse. 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

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

5. HOW TO STORE INSTILLAGEL

Keep out of the sight and reach of children.

Do not use **Instillagel** after the expiry date stated on the folder box. The expiry date refers to the last day of that month.



This medicine does not require any special storage conditions.

Instillagel is provided in a single-use tube that looks like a syringe for injections. Any unused gel remaining in the syringe should be thrown away. 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Instillagel contains:

The active substances per 6 ml are:

- Lidocaine Hydrochloride 125.40 mg
- Chlorhexidine Gluconate 3.14 mg
- Methyl Hydroxybenzoate 3.76 mg
- Propyl Hydroxybenzoate 1.57 mg

The active substances per 11 ml are:

- Lidocaine Hydrochloride 230.00 mg
- Chlorhexidine Gluconate 5.75 mg
- Methyl Hydroxybenzoate 6.90 mg
- Propyl Hydroxybenzoate 2.87 mg

The other ingredients are:

- Hydroxyethylcellulose
- Propylene Glycol
- Sodium Hydroxide
- Purified Water

What Instillagel looks like and contents of the pack

Instillagel is supplied in disposable 6 ml or 11 ml polypropylene syringes with a rubber stopper. Pack sizes of 10 and 100 syringes are available.

Marketing Authorisation Holder

FARCO-PHARMA GmbH
Gereonsmühlengasse 1 - 11
50670 Cologne
Germany

Tel ——— +49/221 59 40 61

Fax ——— +49/221 59 36 14

Manufacturer

Almed GmbH
Motzener Str. 41
12277 Berlin
Germany

Sole Distributor in U.K.

CliniMed Ltd.,
Cavell House, Knaves Beech Way,
Loudwater, High Wycombe, Bucks.,
HP10 9 QY

Is this leaflet hard to see or read?

Telephone +49 221 594061 for an audio-tape, large print leaflet or other formats.

This leaflet was last revised in February 2019.



FARCO