

Instillagel 6 ml, gel

Instillagel 11 ml, gel

Active substances: Lidocaine hydrochloride 1 H₂O, Chlorhexidine digluconate, Methyl-4-hydroxybenzoate(Ph.Eur.), Propyl-4-hydroxybenzoate (Ph.Eur.)

sterile

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

- 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 only. Do not pass it on to others. 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What is **Instillagel 6 ml/11 ml** and what is it used for?
2. What do you need to know before you use **Instillagel 6 ml/11 ml**?
3. How to use **Instillagel 6 ml/11 ml**
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6. Contents of the pack and other information

1. What is Instillagel 6 ml/11 ml and what is it used for?

Sterile gel with a local anesthetic and antiseptic effect.

For instillation.

As a gel for mucous membrane disinfection and for local anesthesia, e.g., during catheterization, probe insertion, including intra-operatively, all forms of endoscopy, fistula catheter replacement, intubation, including for ventilation, for the prevention of iatrogenic damage to the rectum and colon.

Instillagel 6 ml/11 ml is suitable for use in adults and children aged 2 years and above.

2. What do you need to know before you use Instillagel 6 ml/11 ml?

Do not use Instillagel 6 ml/11 ml

- if you are allergic to lidocaine hydrochloride 1 H₂O, chlorhexidine digluconate, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate, or any of the other ingredients of this medicine listed in section 6.
- in the presence of known hypersensitivity to lidocaine and other local anesthetics of the amide type,
- in patients with significant disorders of the cardiac conduction system
- in children under 2 years

Warnings and precautions

Talk to your doctor before using **Instillagel® 6 ml/11 ml**.

Other medicines and Instillagel 6 ml/11 ml

Tell your doctor if you are using, have recently used, or might use any other medicines.

A dose-dependent increase in lidocaine toxicity was observed in animal studies (in mice) when administered at the same time as pethidine.

Pregnancy, breastfeeding, and fertility

Lidocaine should not be used during the first three months of pregnancy unless absolutely necessary. It is unknown whether lidocaine is excreted in breast milk, for which reason breastfeeding should not take place for up to about 12 hours after administration.

Driving and using machines

If this medicine is used during surgery or over extensive areas, the doctor will have to decide on a case-by-case basis whether you may drive or use machines.

Instillagel 6 ml/11 ml contains methyl- and propyl-4-hydroxybenzoate and propylene glycol.

Methyl- and propyl-4-hydroxybenzoate can trigger hypersensitivity reactions, including late reactions.

Instillagel 6 ml contains 3.14 g propylene glycol corresponding to 522.5 mg/ml.

Instillagel 11 ml contains 5.75 g propylene glycol corresponding to 522.5 mg/ml.

Propylene glycol may cause skin irritation.

3. How to use Instillagel 6 ml/11 ml

Unless otherwise prescribed, for urological use.

- a) During catheterization:
Instill 6 ml or 11 ml. After the usual cleaning of the glans and the external urethral orifice, **Instillagel 6 ml/11 ml** is instilled slowly into the urethra and the glans is compressed until the onset of the local anesthetic and antiseptic action.
- b) For cystoscopy and endoscopy:
Instill 11 ml, and if necessary an additional 6 ml or 11 ml. The entire urethra, including the external sphincter, must be covered with the lubricating film and be anesthetized for germ-free and painless insertion of instruments. A penis clamp should be applied in the region of the coronal sulcus.
- c) In case of urethral strictures (stricture division, bougienation):
Instill 11 ml, and if necessary an additional 6 ml or 11 ml, and apply a penis clamp. The required urethral anaesthesia will be achieved after 5–10 minutes.
- d) For disinfection, 6 ml or 11 ml of gel is spread (instilled) on the mucous membrane.

For other applications:

Instill 6 ml or 11 ml slowly into the relevant body orifice and/or spread the gel as evenly as possible on the catheter to be inserted or on the instrument.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Use in children

The systemic absorption of lidocaine may be increased in children and caution is therefore required.

In general, the maximum dose should not exceed 2.9 mg of lidocaine hydrochloride per kg of body weight in children between 2 and 12 years of age. This is equivalent to 1.5 ml of **Instillagel 6 ml/11 ml** per 10 kg of body weight.

If you use more Instillagel 6 ml/11 ml than you should

There is no known information on overdose.
The onset of the full local anesthetic and antiseptic action of **Instillagel 6 ml/11 ml** takes place after 5–10 minutes.

4. Possible side effects

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

Such side effects can include:

- Very rare: allergic reactions (in the most serious cases, anaphylactic shock) to a local anesthetic of the amide type and/or to chlorhexidine
- Very rare: allergic reactions, including late reactions, due to chlorhexidine and/or methyl- or propyl-4-hydroxybenzoate
- Side effects: Not known: in spite of the proven wide safety range of **Instillagel 6 ml/11 ml**, systemic adverse effects of the local anesthetic lidocaine, such as anaphylactic shock, a fall in blood pressure, bradycardia or seizures, are possible in the case of severe urethral damage.

The frequency of these side effects has been classified as very rare (can affect up to 1 in 10,000 people) or not known (cannot be estimated from the available data).

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 to

Federal Institute for Drugs and Medical Devices
Pharmacovigilance Dept.
Kurt-Georg-Kiesinger Allee 3
D-53175 Bonn, Germany
Website: <http://www.bfarm.de>

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

5. How to store Instillagel 6 ml/11 ml

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiration date which is stated on the carton and the container.
Once open, use the disposable syringe immediately and discard any remaining gel.
Do not throw away any medicines in 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 pack and other information

Instillagel 6 ml/11 ml contains

- The active substances are:

	6 ml gel	11 ml gel
Lidocaine hydrochloride 1 H ₂ O	125.40 mg	230.00 mg
Chlorhexidine digluconate	3.14 mg	5.75 mg
Methyl-4-hydroxybenzoate (Ph.Eur.)	3.76 mg	6.90 mg
Propyl-4-hydroxybenzoate (Ph.Eur.)	1.57 mg	2.87 mg
- Other ingredients: Hyetellose, propylene glycol, sodium hydroxide, purified water

What Instillagel 6 ml/11 ml looks like and contents of the pack

Disposable syringes containing 6 ml or 11 ml of gel
Pack sizes:
1 × 6 ml N1, 1 × 11 ml N1,
10 × 6 ml N2, 10 × 11 ml N2,
100 × 6 ml N3, 100 × 11 ml N3

Marketing Authorization Holder and Manufacturer

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