

Package leaflet: Information for the user

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 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 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 Instillagel 6 ml/11 ml is and what it is used for
2. What you need to know before you use Instillagel 6 ml/11 ml
3. How to use Instillagel 6 ml/11 ml
4. Possible side effects
5. How to store Instillagel 6 ml/11 ml
6. Contents of the pack and other information

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

Sterile gel with a local anaesthetic and antiseptic effect.

For instillation.

As a gel for mucous membrane disinfection and for local anaesthesia, e.g. during catheterisation, 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 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 anaesthetics of the amide type,
- in patients with significant disorders of the heart's conduction system,
- in children under 2 years.

Warnings and precautions

Instillagel must not come into contact with the eyes due to the risk of eye damage. In case of contact with the eyes, the eyes should be thoroughly rinsed with water immediately. Seek medical attention immediately if irritation, reddening or pain in the eye or visual impairments occur.

Severe cases of permanent corneal injury (damage of the surface of the eye), which may require corneal transplantation, have been reported in patients in whom inadvertent contact of the eyes with

similar medicinal products occurred during surgical procedures under full anaesthesia (deep, pain-free sleep).

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, breast-feeding and fertility

Lidocaine should not be used during the first three months of pregnancy unless absolutely necessary. It is not known whether lidocaine passes into human milk; for this reason, the woman should not breast-feed for up to around 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 may cause hypersensitivity reactions (possibly delayed).

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

Instillagel 11 ml contains 5.75 g propylene glycol equivalent 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 catheterisation:

Instil 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 local anaesthetic and antiseptic effect has set in.

b) during cystoscopy and endoscopy:

Instil 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 anaesthetised for germ-free and painless insertion of instruments. A penis clamp should be applied in the region of the coronal sulcus.

c) in urethral strictures (stricture division, bougienation):

Instil 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) evenly on the mucous membrane.

For other applications:

Instil 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 are no known cases of overdose.

The onset of the full local anaesthetic and antiseptic action of Instillagel 6 ml/11 ml is achieved 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 anaesthetic 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
- Not known: Despite the proven wide safety range of Instillagel 6 ml/11 ml, systemic adverse effects of the local anaesthetic lidocaine, such as anaphylactic shock, a fall in blood pressure, bradycardia or seizures, are possible in the case of severe urethral damage
- Not known: Corneal injury (damage of the surface of the eye) and permanent eye damage including permanent visual impairment (after inadvertent contact with the eye during surgical procedures of the head, face and neck) in patients under full anaesthesia (deep, pain-free sleep)

The frequency of these side effects has been classified as very rare (may affect up to 1 in 10,000 people) or as 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 via the

Federal Institute for Drugs and Medical Devices (BfArM)
Pharmacovigilance Dept.
Kurt-Georg-Kiesinger-Allee 3
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 expiry date which is stated on the carton and the container.

Once open, use the disposable syringe immediately and discard residual gel.

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 protect the environment.

6. Contents of the pack and other information

What 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

- The other ingredients are:

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 Authorisation Holder and Manufacturer

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