

# Instillagel® 6 ml/11 ml

sterile

Instillagel® 6 ml

Instillagel® 11 ml

**Active substances:** lidocaine hydrochloride 1H<sub>2</sub>O, chlorhexidine digluconate, methyl-4-hydroxybenzoate, propyl-4-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 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**
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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 1H<sub>2</sub>O, 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

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 is excreted in human milk, for which reason breast-feeding 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. Propylene glycol can 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 ca-

theter 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 anaesthetic and antiseptic effect 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 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: in spite of 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.

The frequency of these side effects has been classified as very rare (can 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

Bundesinstitut für Arzneimittel und Medizinprodukte  
[Federal Institute for Drugs and Medical Devices]

Abt. Pharmakovigilanz [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 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 1H <sub>2</sub> O	125.40 mg	230.00 mg
Chlorhexidine digluconate	3.14 mg	5.75 mg
Methyl-4-hydroxybenzoate	3.76 mg	6.90 mg
Propyl-4-hydroxybenzoate	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 x 6 ml N1; 1 x 11 ml N1
	10 x 6 ml N2; 10 x 11 ml N2
	100 x 6 ml N3; 100 x 11 ml N3

##### Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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