

# Instillagel<sup>®</sup>, gel, 2g/0.25g

## Lidocaine HCL Monohydrate/Chlorhexidine Digluconate Solution

Lidocaine hydrochloride monohydrate 20.9mg/ml and Chlorhexidine digluconate solution 2.78mg/ml

### What is in this leaflet

1. What *Instillagel*<sup>®</sup> is used for
2. How *Instillagel*<sup>®</sup> works
3. Before you use *Instillagel*<sup>®</sup>
4. How to use *Instillagel*<sup>®</sup>
5. While you are using it
6. Side effects
7. Storage and Disposal of *Instillagel*<sup>®</sup>
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

### What *Instillagel*<sup>®</sup> is used for

Sterile gel with a local anesthetic and antiseptic effect.

It is used during various procedures as a local anesthetic.

*Instillagel*<sup>®</sup> ml is suitable for use in adults only.

### How *Instillagel*<sup>®</sup> works

*Instillagel*<sup>®</sup> numbs the parts of the body it is applied to (local anaesthetic).

It also provides lubrication to ease an instrument into a body cavity during examination. This makes it easier for your doctor to look inside these parts of your body without causing you discomfort.

The gel contains substances (antiseptics) to reduce the risk of infection.

### Before you use *Instillagel*<sup>®</sup>

#### - When you must not use it

Do not use *Instillagel*<sup>®</sup>

- if you are allergic to lidocaine hydrochloride 1 H<sub>2</sub>O, chlorhexidine digluconate, methyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate, or any of the other ingredients of this medicine.
- if you ever had a reaction to a local anaesthetic
- in patients with irregular heartbeats
- in children

#### *Pregnancy and lactation*

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.

#### - Before you start to use it

*Instillagel*<sup>®</sup> contains methyl- and propyl-4-hydroxybenzoate and propylene glycol.

Methyl- and propyl-4-hydroxybenzoate can trigger allergic reactions, including delayed reactions.

*Instillagel*<sup>®</sup> 6ml contains 3.14 g propylene glycol corresponding to 522.5 mg/ml.

*Instillagel*<sup>®</sup> 11 ml contains 5.75 g propylene glycol corresponding to 522.5 mg/ml.

Propylene glycol may cause skin irritation.

Talk to your doctor before using *Instillagel*<sup>®</sup>:

- if you have damaged skin
- if the moist lining (mucous membrane) of the application site (mouth, bladder, vagina, colon or rectum) is damaged
- if you have heart problems
- if you have liver problems (hepatic insufficiency, liver failure, cirrhosis)
- if you suffer from epilepsy
- if your urethra is damaged

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.

#### - Taking other medicines

Tell your doctor if you are using, have recently used, or might use any other medicines, including medicines obtained without a prescription.

Tell the person who is going to give you *Instillagel* if you are taking any medicines for treating irregular heartbeats.

### How to use *Instillagel*<sup>®</sup>

#### - How much to use

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

a) For urethral probe examination and catheterization:  
Instill 6 or 11 ml. After the normal cleaning of the glans and the external urethral orifice, instill *Instillagel* slowly into the urethra, keeping the glans compressed, until the local anaesthetic and disinfectant action has set in.

b) For cystoscopy:  
Instill 11 ml, and possibly an additional 6 or 11 ml. The entire urethral including the external sphincter must be covered with the lubricating film and anaesthetized for germ-free and painless introduction of instruments. A penis clamp is attached in the region of the sulcus coronarius.

The anaesthetic takes about 5 to 10 minutes to work after the gel has been applied.

#### - When to use it

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

#### - How long to use it

Continue using *Instillagel*<sup>®</sup> for as long as your doctor recommends.

#### - If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

#### - If you use too much (overdose)

No known information available.

The onset of the full local anesthetic and antiseptic action of *Instillagel*<sup>®</sup> takes place after 5–10 minutes.

In the unlikely event you are given more Instillagel than you should, you may experience the following:

- fits (convulsions)
- difficulty breathing
- your heart stopping beating (cardiac arrest)

Inform your doctor immediately if you notice any of these symptoms. If you have any further questions on the use of this product, ask your doctor.

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using *Instillagel*®.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Instillagel*® to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

The ability to drive and to operate machinery can be impaired after the use of *Instillagel*.

**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 delayed 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*®, systemic adverse effects of the local anesthetic lidocaine, such as anaphylactic shock, a fall in blood pressure, slower heart rate or fits

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).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

**Storage and Disposal of *Instillagel*®**

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C.

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.

- Disposal

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.

**Product Description**

- What it looks like

Disposable syringes containing 6 ml or 11 ml of gel

Pack sizes:

10 × 6 ml, 10 × 11 ml,

- Ingredients

- Active ingredients

Lidocaine hydrochloride monohydrate  
Chlorhexidine digluconate solution

- Inactive ingredients

Methyl-4-hydroxybenzoate, Propyl-4-hydroxybenzoate,

Hydroxyethylcellulose, propylene glycol, sodium hydroxide, purified water

- MAL number(s):  
MAL\*\*\*\*\*

**Manufacturer**

Klosterfrau Berlin GmbH,  
Motzener Strasse 41,  
12277 Berlin, Germany.

**Product Registration Holder**

Medispec (M) Sdn Bhd  
B-1-07, Jalan SS 25/22,  
Taman Mayang,  
47301 Petaling Jaya, Selangor.

**Date of revision**

18.06.25

**Serial number**

NPRA (R1)24/035