

Package leaflet: Information for the patient

Instillido 20 mg/ml gel in a prefilled syringe

Lidocaine hydrochloride (as lidocaine hydrochloride monohydrate)

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

- Keep this leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor, pharmacist or healthcare professional.
- 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, pharmacist or healthcare professional. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Instillido is and what it is used for

Instillido is a sterile gel that contains the active substance lidocaine hydrochloride (as lidocaine hydrochloride monohydrate). It will be referred to as lidocaine throughout this leaflet.

Lidocaine has a local anaesthetic effect and is used to numb the parts of the body the gel is applied to. It stops the nerves from being able to pass pain messages to the brain and so stops you feeling pain.

Due to its **local anaesthetic effect** and the **lubricant properties** for catheters, endoscopes or other medical instruments, Instillido is designed to relieve discomfort and ease the process during certain types of examinations or procedures. Instillido is used

- for instillation (insertion) into the urethra before a catheter is inserted or replaced and for cystoscopy, when a doctor inserts a tube through the urethra to visualise your bladder;
- for proctoscopy or rectoscopy (medical procedures in which an instrument called an endoscope is used to examine the anal cavity or rectum). During this procedure, Instillido is instilled into the anal cavity/rectum and/or the instrument used is lubricated with Instillido before insertion.

Due to its **local anaesthetic effect**, Instillido is also used,

- to help relieve the pain from inflammation of the urinary bladder.

Instillido is indicated in adults, adolescents (above 12 years of age) and children from 2 to 12

years.

Your doctor will explain to you which specific procedure or condition Instillido is being used for.

It is usually administered by a doctor, but it can also be administered by you or your carer, e.g. for self-catheterisation (see section 3. "How to use Instillido").

2. What you need to know before you use Instillido

Do not use Instillido

- if you are allergic to lidocaine hydrochloride or to any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to certain other local anaesthetics (of the amide type).
- in children below 2 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Instillido.

Before using this medicine, your doctor needs to know if you have, or have had, any of the following:

- if you have any wounds, injury to the mucous membranes or an ulcer/inflammation in or around the proposed application use.
- if your liver or kidney function is impaired, if you are acutely ill or in a weak condition or have sepsis ("blood poisoning"). Your doctor may reduce your dose of Instillido.
- if you have a slow heartbeat or a heart or respiratory tract dysfunction (problems with your airways).
- if you have a weak heart (heart failure) or heart conduction disturbances (atrioventricular block).
- if you suffer from medical shock.
- if you are prone to convulsions (seizures) or if you have epilepsy.
- if you suffer from a certain muscle disease (myasthenia gravis).
- if you have a rare inherited illness that affects the blood called "glucose-6-phosphate dehydrogenase deficiency".
- if you have a problem with blood pigment levels called "methaemoglobinaemia".
- if you suffer from porphyria (a blood formation disorder).
- if you are on treatment with certain medications to treat heart rhythm disorders, known as class III antiarrhythmics (e.g. amiodarone), as the effects on the heart may be increased. See also the section "Other medicines and Instillido".

Also tell your doctor if you use other medicines containing lidocaine frequently and/or at high doses, as this may lead to serious side effects.

If a lot of Instillido is instilled into the urethra and a large amount of the gel gets into the bladder or if the urethra is ulcerated/inflamed, this may generally lead to increased absorption of lidocaine through the mucous membranes, particularly in children and elderly patients, resulting in serious side effects (see also section 3, "If you have been administered / if you use more

Instillido than you should").

Other medicines and Instillido

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines. Lidocaine may affect or be affected by other medicines.

In particular, tell your doctor if you are taking/using any of the following:

- **Antiarrhythmics** - medicines to treat an irregular heartbeat (e.g. mexiletine, amiodarone).
- **Calcium channel blockers** - medicines taken for heart conditions or high blood pressure (e.g. diltiazem, verapamil).
- **Beta-blockers** (e.g. propranolol, metoprolol) - for the treatment of high blood pressure or angina (chest pain).
These medicines may have an enhanced effect on the heart.
- other medicines containing **lidocaine** or certain other **local anaesthetics** (of the amide type), as they may enhance their respective effects in an unpredictable manner.
- **Cimetidine** to treat hyperacidity, stomach and duodenal ulcers. Using this medicine at the same time may increase the risk of side effects.
- **Fluvoxamine** to treat depression.
- **Erythromycin** (antibiotic).
- Protease inhibitors used to treat HIV (e.g. **ritonavir**).
- Medicines used to treat infections, called **sulphonamides** and **nitrofurantoin**.
- Medicines used to treat epilepsy, called **phenytoin** and **phenobarbital**.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

During pregnancy and breast-feeding, Instillido should only be used after your doctor has carefully considered the benefits and risks.

Driving and using machines

Effects on the ability to drive and use machines are unlikely, but cannot be completely ruled out in cases of increased individual sensitivity. If you feel drowsy or dizzy or if you have vision disturbances, do not drive or use any tools or machinery.

3. How to use Instillido

It is usually administered by a doctor with appropriate training and relevant experience.

If you are treating yourself, e.g. for self-catheterisation (inserting a small plastic tube (catheter) into one's own urethra), always use this medicine exactly as your doctor has told you and follow the instructions below for how to use the gel. Check with your doctor if you are not sure.

Instillido starts to work within 5-15 minutes after the application. The effect usually lasts 20 to 30 minutes.

Dose

Your doctor will decide on the most suitable dosage for your particular case according to your age and medical condition as well as for the site of application, the method used and your response.

The recommended dose is

Adults**For instillation (insertion) into the urethra***Male patients*

For adequate pain relief, 20 ml of gel is usually required.

When anaesthesia is especially important, e.g. during sonography or cystoscopy, your doctor may instil a larger quantity of gel (up to 40 ml).

For catheterisation, small volumes (5-10 ml) are usually adequate for lubrication.

Female patients

The doctor will adapt the amount of gel to be inserted to the individual anatomical conditions of the urethra. Usually 5-10 ml of gel are instilled in small portions to fill the whole urethra.

For pain relief from inflammation of the urinary bladder

10-20 ml are usually required for adequate pain relief.

The doctor decides on the frequency and duration of use based on your condition and symptoms.

The maximum dose is: 20 ml gel once a day.

Proctoscopy and rectoscopy

For adequate pain relief, your doctor will usually instil 10-20 ml of gel into the anal cavity/rectum and will apply a small amount to lubricate the endoscope.

Maximum dosage

The dose depends on the application site. A safe dose for use in the urethra and bladder in adults is 40 ml gel (approximately 800 mg lidocaine hydrochloride). The maximum recommended daily dose is approximately 800 mg lidocaine hydrochloride.

Special population

Your doctor may decide to reduce the dose if you are elderly, acutely ill or debilitated, if you have liver or kidney problems or if you have sepsis ("blood poisoning"). A maximum dose of 2.9 mg/kg body weight lidocaine hydrochloride must not be exceeded.

Use in children and adolescents*Children < 2 years of age*

Instillido must not be used in children < 2 years of age.

Children (2-12 years) and adolescents (above 12 years of age)

The doctor will determine the dose depending on the child's age, weight and physical condition.

A maximum dose of 2.9 mg/kg body weight lidocaine hydrochloride must not be exceeded in children (2-12 years).

Method of administration

The pre-filled graduated syringes are available with 6 ml or 11 ml gel. Your doctor will choose the appropriate size depending on the amount you need.

Each graduation on the syringe is equivalent to approximately 1 ml of gel (20.1 mg lidocaine hydrochloride)

For (self-)catheterisation (urethral use)

Follow these directions carefully:

1. Wash your hands. Clean and disinfect the genital area.
2. When ready to use, open the blister.
3. Before removing the tip cap from the end of the syringe, press in the plunger to remove any resistance that may be present. This helps ensure that the syringe will empty easily and uniformly. [Figure 1]
4. Remove the tip cap from the syringe. The syringe is now ready for use. [Figure 2]
5. Insert the nozzle into the opening of the urethra and press the plunger slowly and evenly to push out the gel into the urethra. [Figure 3]
6. Wait a few minutes after instillation of the gel for the anaesthetic to take full effect. The full anaesthetic effect will occur within 5 to 15 minutes after complete instillation.

Figure 1:

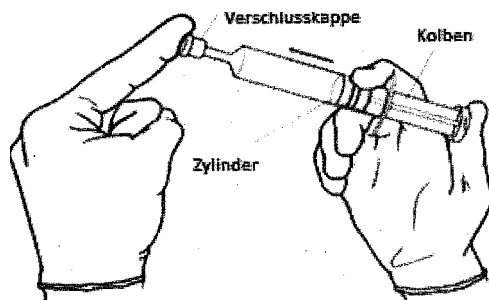


Figure 2:

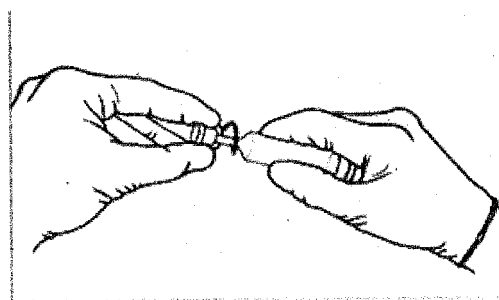
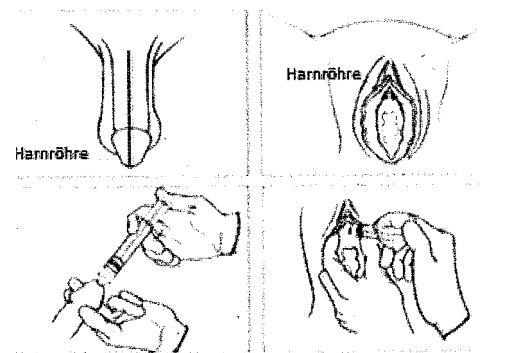


Figure 3:

Male patient: Female patient:



| | |
|-----------------|---------|
| Verschlusskappe | cap |
| Zylinder | barrel |
| Kolben | plunger |
| Harneroehre | urethra |

For cystoscopy

Your doctor will administer this medicine in the urethra and/or apply it to the endoscope auf

For proctoscopy and rectoscopy

Your doctor will administer this medicine in the anal cavity/rectum and/or apply it to the endoscope.

The syringe is for single use only.

Use immediately after opening the blister.

The syringe and any gel not used in a single application must be discarded.

Duration of treatment

For examinations/procedures, Instillido is usually only used for one or two doses or for a short course of treatment.

If you have been prescribed Instillido for self-administration, your doctor will decide how long you should continue to use this medicine depending on your condition.

If you have been administered/if you use more Instillido than you should

Administration of Instillido by a doctor

Since this medicine is usually administered to you by a trained doctor, it is unlikely that you will be given too much Instillido. However, if you think you have been given too much medicine or you begin to experience the overdose symptoms listed below, you must tell the person giving you Instillido immediately. Your doctor will know how to manage these symptoms and give you any necessary treatment.

Administration of Instillido by yourself or a caregiver for self-catheterisation

Whether you develop symptoms of an overdose or not depends on the level of this medicine present in your blood. The more lidocaine is in your blood, the more severely you might experience symptoms of an overdose.

Normally, only small amounts of the active ingredient lidocaine are absorbed into the blood from Instillido. Too much lidocaine can be absorbed if the surface being treated is damaged.

The first symptoms of an overdose are, for example,

Problems with hearing, vision, speaking and/or coordination of movements, yawning, restlessness, dizziness, nausea and vomiting.

In case of overdose, contact a doctor or hospital emergency department immediately, even if there are no symptoms.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you have used a larger amount of Instillido 20 mg/ml gel, contact your doctor, pharmacist or the Poison Centre (070/245245) immediately.

4. Possible side effects

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

Lidocaine is generally well tolerated, provided the medicine is used as directed in section "3. How to use Instillido" and the necessary precautions are taken (see section "2. What you need to know before you use Instillido").

Some side effects may be serious. Seek immediate medical help if you have an allergic (hypersensitivity) reaction causing:

- Swelling of the hands, feet, face, lips, mouth, tongue or throat
- Difficulties in breathing
- Shortness of breath due to narrowing of the airways (bronchospasm)
- Skin problems such as itchy skin or rash
- Hives
- Drop in blood pressure and shock

These side effects are rare (may affect up to 1 in 1000 people treated).

Other side effects include

Very rare (may affect up to 1 in 10,000 people treated)

- administration site irritation.

Symptoms of an overdose may occur due to accelerated absorption (from the site of application into the blood) or overdose (see also section 3. "If you have been administered / if you use more Instillido than you should").

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 to the Federal Institute for Drugs and Medical Devices, Pharmacovigilance Department, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de.

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

5. How to store Instillido

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 label/blister/carton after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Keep the blisters in the outer carton in order to protect from light. Keep the pre-filled syringe in its unopened blister until use.

Instillido syringes are intended for single use. The syringe and any gel not used in a single application must be discarded.

Never dispose of medicines via waste water (e.g. not in the toilet or sink). Ask your pharmacist how to dispose of the medicine when you no longer use it. These measures will help protect the environment. Further information can be found at www.bfarm.de/arzneimittelentsorgung.

6. Contents of the pack and further information

What Instillido contains

- The active substance is lidocaine, present as lidocaine hydrochloride monohydrate. 1 ml gel contains 20.1 mg lidocaine hydrochloride equivalent to 21.5 mg lidocaine hydrochloride monohydrate.

6 ml pre-filled syringe

One pre-filled syringe with 6 ml gel contains 120.6 mg lidocaine hydrochloride.

11 ml pre-filled syringe

One prefilled syringe with 11 ml gel contains 221.1 mg lidocaine hydrochloride.

- The other ingredients are hypromellose, sodium hydroxide 5N (for pH adjustment), purified water.

What Instillido looks like and contents of the pack

Clear, nearly colourless, sterile gel.

Instillido is available in a sterile pre-filled syringe containing 6 ml or 11 ml of gel. The syringes are individually packed in a sterile, transparent blister pack.

Each graduation on the syringe is equivalent to approximately 1 ml of gel (20.1 mg lidocaine hydrochloride).

Pack sizes

Box of 10 pre-filled syringes with 6 ml gel each

Box of 10 pre-filled syringes with 11 ml gel each

Not all pack sizes may be marketed.

Marketing authorisation holder

FARCO-PHARMA GmbH
Gereonsmühlengasse 1-11
50670 Cologne
Germany

Manufacturer

Klosterfrau Berlin GmbH
Motzener Str. 41
12277 Berlin, Germany

This medicinal product is authorised in the Member States of the European Economic Area (EEA) under the following names:

| Member state | Name of the medicinal product |
|-----------------------|---|
| Denmark | Instillido |
| Germany | Instillido 20 mg/ml Gel in einer Fertigspritze |
| France | Glydo 20 mg/ml gel |
| Netherlands | Instillido 20 mg/ml gel |
| Sweden | Instillido 20 mg/ml gel |
| UK (Northern Ireland) | Glydo 20 mg/ml gel in pre-filled syringe |
| Norway | Instillido 20 mg/ml gel i forhåndsfylt sprøyte |
| Finland | Instillido 20 mg/ml geeli |
| Belgium | Instillido 20 mg/ml gel |
| Croatia | Instillido 20 mg/ml gel |
| Spain | Instillido 20 mg/ml gel en jeringa precargada |
| Poland | Instillido, 20 mg/mL, żel w ampulko-strzykawce |
| Estonia | Instillido 20 mg/ml gel |
| Lithuania | Lidocaine hydrochloride Instillido 20 mg/ml gelis |
| Slovenia | Instillido 20 mg/ml gel v napolnjeni injekcijski brizgi |
| Romania | Instillido 20 mg/ml gel |
| Bulgaria | Instillido 20 mg/ ml gel |

This leaflet was last revised in May 2023