

PACKAGE LEAFLET: INFORMATION FOR THE USER**Cathejell with Lidocaine – anaesthetising gel (sterile single-use form)**

Lidocaine hydrochloride, chlorhexidine dihydrochloride

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What *Cathejell* is and what it is used for

Cathejell is a sterile gel used as a lubricant for catheters, endoscopes or other medical instruments.

It is intended for use on mucous membranes. Due to its lubricant effect, local anaesthetic and antibacterial action, it is designed to relieve pain during such procedures and prevent most infections. The effect sets in as early as 5 – 10 minutes after application and lasts for 20 – 30 minutes.

Cathejell is indicated in adults, adolescents (aged 12 to 18 years) and children from 2 to 11 years.

As a local anaesthetic, it contains *lidocaine*. In surface anaesthesia, it generally takes effect in about 3-5 minutes. In inflamed tissue, the effect is reduced.

To avoid infections at the application site, *Cathejell* contains *chlorhexidine*. This agent disinfects and acts against many bacteria, some fungi and viruses.

2. What you need to know before you use *Cathejell***Do not use *Cathejell***

- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of *Cathejell*

- if you are allergic (hypersensitive) to certain other local anaesthetics (of the amide type),
- in children below 2 years of age,
- in bulbocavernosus reflux (an injury to the thin urethral lining, which may cause the lubricant to infiltrate into erectile tissue, where absorption may occur),
- in patients with a severely weak heart, extremely slow heartbeat, heart conduction disturbances (AV block), shock due to heart failure or reduced blood volume.

Please talk to your doctor if one or more of these statements apply to you, or have ever applied to you in the past.

Warnings and precautions

Talk to your doctor or pharmacist before using *Cathejell*

- if used frequently and at high doses, as this may lead to severe side effects. Increased absorption of *lidocaine* is likely when used in the bronchial area, which is associated with a particularly high risk of overdose.
- if you have any wounds, injury to the mucous membranes or an ulcer/inflammation in or around the proposed application site,
- if your liver or kidney function is severely impaired,
- if you have heart or respiratory tract dysfunction,
- in elderly, debilitated or acutely ill patients,
- if you are prone to seizures,
- if you are suffering from a certain muscle disease (myasthenia gravis),
- 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 enhanced
- if you suffer from porphyria (a blood formation disorder).

Swallowing difficulties may occur when using *Cathejell* in the mouth and throat region. There is a risk of inhaling the gel (aspiration). Numbness of the tongue or mouth area can lead to a bite injury.

If the contents of more than one syringe are inserted into the urethra, if a large amount of gel gets into the bladder or if the urethra is ulcerous / inflamed, this may generally lead to increased absorption of *lidocaine* through the mucous membranes, particularly in children and elderly patients, resulting in severe side effects (see also section 3, “*If you use more Cathejell than you should*”).

Cathejell must not come into contact with the eyes.

In general anaesthesia, a lubricant without *lidocaine* should be preferred.

Other medicines and *Cathejell*

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Cathejell should not be used at the same time as other medicines containing *lidocaine* or certain other local anaesthetics (of the amide type), as this may enhance their respective effects in an unpredictable manner.

As there may be an enhanced effect on the heart, *lidocaine* should be used with caution in patients also receiving medication used to treat heart rhythm disorders (antiarrhythmics, e.g. mexiletine, tocainide), high blood pressure (beta-blockers, such as propranolol) or calcium channel blockers (e.g. diltiazem, verapamil).

No specific interaction studies have been performed with *lidocaine* and class III antiarrhythmics; however, caution is advised (see also “*Take special care with Cathejell*”), as the effects on the heart may be enhanced.

If you are taking cimetidine (which blocks stomach acid production), discuss this with your doctor before treatment with *Cathejell*. Using such medicines at the same time can increase the risk of side effects.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

During pregnancy and breast-feeding, *Cathejell* should only be used after your doctor has carefully considered the benefits and risks and has decided on your individual dose. Repeated use during pregnancy and breast-feeding is not recommended.

Please note that there should be a 12-hour interval between using *Cathejell* and subsequent breast-feeding.

Women planning a pregnancy or who think they are pregnant should tell their doctor.

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.

3. How to use *Cathejell*

This medicine should only be used by a doctor or medically trained nursing staff. The dose is individually adjusted.

The following dosing information is a guideline; the doctor’s experience and knowledge about the patient’s physical condition are important when calculating the appropriate dose. The degree of absorption is particularly high in the bronchial tree.

Use in the urethra before inserting a catheter, endoscope or other medical instruments

The accordion syringes (hereafter called ‘syringes’) contain 12.5 g or 8.5 g gel, of which approximately 10 g and 6 g respectively is inserted into the urethra during instillation.

Dosage recommendation:

Adult men

The 12.5 g syringes are generally needed. The contents of one syringe are sufficient for sufficient filling of the male urethra; no more than one syringe should be instilled. The effect sets in as early as 5 – 10 minutes after application and lasts for 20 – 30 minutes.

Women, children (2-12 years) and adolescents (below 18 years)

The effect of *Cathejell* is not so well demonstrated and therefore the need to use it should be assessed by the doctor. Specific dosage recommendations cannot be given for these groups of patients.

The systemic absorption of Lidocaine can be increased in children and caution is accordingly required. In general, the maximum dose in children aged 2 to 11 years of 2.9 mg/kg Lidocaine hydrochloride should not be exceeded.

Children under 2 years:

Cathejell must not be used in children under 2 years (see section 4.3).

Dosage recommendations for risk patients:

The dosage must be adjusted accordingly in elderly, debilitated and acutely ill patients, as well as in cases of impaired hepatic function or severe renal dysfunction (see sections 4.4 and 5.2). The maximum dose must be calculated in mg lidocaine hydrochloride/kg body weight (2.9 mg lidocaine hydrochloride/kg BW).

Method of administration:

For use in the urethra

1. Clean and disinfect the external opening of the urethra
2. Peel off the paper from the transparent blister cover until you see the tapered end of the blister
3. Snap off the tip; if possible, while it is still in the blister
4. Remove the tip completely, so that it cannot be inserted into the urethra by mistake
5. Squeeze out a drop of gel, so that the application nozzle can be inserted more easily
6. Slowly insert the gel by gently pressing on the syringe

Cathejell syringes are intended for single use. Discard any remaining gel.

Use for anaesthesia in general and tracheal intubation

Adults and adolescents aged 12 years and older:

Evenly distribute approximately 5 ml over the bottom third of the tube. To avoid desiccation, the gel is not applied to the instrument until immediately prior to use. The gel should not get inside the tube lumen.

For adults of normal body weight, the maximum dose is 16 g *Cathejell*.

Dosage recommendations for children up to 11 years:

The systemic absorption of Lidocaine can be increased in children and caution is accordingly required. In general, the maximum dose of 2.9 mg/kg BW Lidocaine hydrochloride should not be exceeded in children aged 2 to 11 years.

Children below 2 years:

Cathejell must not be used in children under 2 years (see section 4.3).

Dosage recommendations for risk patients

The dosage must be adjusted accordingly in elderly, debilitated and acutely ill patients, as well as in cases of impaired hepatic function or severe renal dysfunction (see sections 4.4 and 5.2). The maximum dose must be calculated in mg lidocaine hydrochloride/kg body weight (2.9 mg lidocaine hydrochloride/kg BW).

Method of administration:

For distribution over probes, endoscopes and tubes.

Cathejell syringes are intended for single use. Discard any remaining gel.

If you use more *Cathejell* than you should

As this medicine is administered by a doctor or medically trained nursing staff, no overdose is likely.

However, should an overdose occur, e.g. if the amount of gel used has not been optimally adjusted to suit your needs, if a large amount of gel gets into the bladder, or if your mucous membranes are inflamed, ulcerous or injured, this can lead to increased absorption of lidocaine, resulting in disturbances of the central nervous system or cardiovascular system. In particular, this also applies if you have been using other local anaesthetics at the same time.

Excitation / depression of the central nervous system may occur in the event of an overdose, which may manifest as symptoms such as nervousness, dizziness, drowsiness and trembling. First signs of an overdose may be numbness of the tongue, eye twitching, dizziness or tiredness.

Side effects of the cardiovascular system, such as slowed pulse, poor heart function or a drop in blood pressure, normally occur only at very high blood concentrations of *lidocaine*.

Respiratory paralysis and cardiovascular failure may occur in the event of a massive overdose with *lidocaine*.

If signs of an overdose occur, please consult a doctor immediately.

You can find further information for healthcare professionals at the end of this leaflet.

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

4. Possible side effects

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

The side effects can be:

- Very common ($\geq 1/10$)
- Common ($\geq 1/100$, $< 1/10$)
- Uncommon ($\geq 1/1,000$, $< 1/100$)
- Rare ($< 1/10,000$)
- Very rare ($< 1/10,000$)
- Not known (cannot be estimated from the available data)

Side effects rarely occur after the use of *Cathejell*, provided that the product is used as directed in the dosage recommendations/recommendations for use and the necessary precautions are taken (see section 2).

Effects on the central nervous system and cardiovascular system:

These are mainly due to rapid absorption, overdose or hypersensitivity.

The following symptoms may occur:

Nervousness, dizziness, blurred vision or trembling, drowsiness, unconsciousness and respiratory arrest, drop in blood pressure, slow heart rate, cardiac arrest. For the treatment of side effects, see section “*If you use more Cathejell than you should*”.

General disorders and local reactions

As a local reaction, hoarseness can occur when used as a lubricant for the endotracheal (airway) tube.

As only low *lidocaine* blood levels are likely during use in urology, no other systemic side effects are expected to occur after instilling *Cathejell* into the urethra.

Immune system disorders

Local hypersensitivity reactions occur in rare cases, such as redness, stinging or itching and / or systemic reactions to *lidocaine* and/or *chlorhexidine*, although severe reactions too (often accompanied by a drop in blood pressure, dizziness, nausea and possibly shortness of breath), including anaphylactic shock, cannot be ruled out.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reaction via:

Bundesamt für Sicherheit im Gesundheitswesen

Traisengasse 5

1200 WIEN

ÖSTERREICH

Fax: + 43 (0) 50 555 36207

Website: <http://www.basg.gv.at/>

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

5. How to store *Cathejell*

Keep the blister in the outer carton, in order to protect from light.

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

Do not use *Cathejell* after the expiry date which is stated on the outer carton after <<EXP>>. The expiry date refers to the last day of the month.

Cathejell syringes are intended for single use. Discard any gel remaining in partially emptied syringes.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What *Cathejell* contains

- The active substances are: lidocaine hydrochloride, chlorhexidine dihydrochloride
1 g gel contains 20 mg lidocaine hydrochloride and 0.5 mg chlorhexidine dihydrochloride.
- The other ingredients are: hydroxyethylcellulose, glycerol, sodium lactate solution, water for injections.

What *Cathejell* looks like and contents of the pack

Sterile single-use form. Clear, water-soluble gel in accordion syringes containing 8.5 g or 12.5 g. The individual syringes are packed in blisters and steam sterilised. The blister strips are packed in outer cartons of 1, 5 or 25 syringes.

1, 5 and 25 accordion syringes with 12.5 g gel in an outer carton

5 and 25 accordion syringes with 8.5 g gel in an outer carton.

Marketing Authorisation Holder and Manufacturer

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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The following information is intended for medical or healthcare professionals only:

Emergency procedures in the event of an overdose:

Treatment of intoxication in the CNS region (convulsions, CNS depression) or the cardiovascular system is symptomatic, e.g. with administration of anticonvulsants and/or emergency cardiopulmonary support:

- immediate suspension of *lidocaine* administration
- maintenance of airway patency
- oxygen administration until all vital functions have normalised
- monitoring of blood pressure, pulse and pupil width

Other possible countermeasures:

- For acutely serious hypotension: elevation of the legs and slow IV injection of a beta-sympathomimetic (e.g. 10 – 20 drops per minute of a 1 mg isoprenaline solution in 200 ml glucose solution 5%) and additional volume substitution
- For increased vagal tone (bradycardia), 0.5 – 1.0 mg atropine is administered IV

- Convulsions lasting for more than 30 seconds are treated by administering an anticonvulsant (thiopental sodium 1-3 mg/kg IV or diazepam 0.1 mg/kg BW IV)
- Persistent seizures can be controlled by injecting a muscle relaxant (e.g. succinylcholine (suxamethonium) 1 mg/kg BW).