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## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Cathejell Lidocaine 2% Gel

Lidocaine Hydrochloride

**Read all of this leaflet carefully before you start using this medicinal product 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 a healthcare professional.
- If you get any side effects, talk to your doctor or a healthcare professional. 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 applied to mucous membranes, has a local anaesthetic effect in addition to the lubricant effect and is to alleviate pain during these interventions in that way. The effect sets in after only 5 - 10 minutes and continues for 20 - 30 minutes.

Cathejell is used on adults, adolescents and children (aged 2 - 12 years).

It contains lidocaine for local anaesthetisation (local anaesthetic). Its effect is reduced in inflamed tissue.

#### 2. What you need to know before you use Cathejell

##### Do not use Cathejell

- If you are allergic to lidocaine hydrochloride or 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),
- On children under the age of 2 years
- In the event of bulbocavernous reflux (an injury of the thin mucous membrane of the urethra, which may result in lubricant being washed into the cavernous body and being absorbed there),
- In the event of severe cardiac insufficiency, a strongly decelerated heartbeat, impaired cardiac stimulus conduction (AV block), shock due to cardiac failure or reduced blood volume.

Talk to your doctor if one or several of these factors are or were true for you.

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## Warnings and precautions

Talk to your doctor or a healthcare professional before using Cathejell, in particular

- If you have severe liver or kidney dysfunction
- If the function of your heart or your respiratory organs is impaired
- If application is repeated or a high dose is used because this may result in severe side effects. When it is used in the bronchial system (bronchoscopy), an increased absorption of lidocaine and therefore an especially high overdose risk are to be expected.
- If you have wounds, injured mucous membranes or an ulcer or inflammation in the area of intended application; mucous membrane injuries result in an increased absorption of lidocaine into the bloodstream.
- If you are elderly, weak or are acutely sick
- If you are prone to seizures
- If you have a certain muscle disorder (myasthenia gravis) which is often associated with an increased sensitivity to local anaesthetics
- If you are treated with certain medicines for the treatment of cardiac arrhythmias, so-called class III antiarrhythmics (e.g. amiodarone) because the effects on the heart may be increased
- If you have porphyria (impaired formation of blood cells), which could be aggravated by lidocaine.

When Cathejell is applied in the oral cavity or the pharynx, this may impair swallowing. There is the risk of an aspiration of gel. Numbness of the tongue or the mouth can result in bite injuries.

If the content of more than one syringe is introduced in the urethra, a considerable quantity of gel gets in the urinary bladder, or if the urethra is inflamed/ulcerous, this may result in general - but particularly in children and elderly patients - in an increased absorption of lidocaine through the mucous membrane and consequently in severe side effects (see also section 3. "If a larger quantity of Cathejell was used than prescribed").

Cathejell must not get in contact with the eyes.

A lubricant without lidocaine is to be preferred for general anaesthesia.

## Other medicines and Cathejell

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

Cathejell should not be used concomitantly with medicines which contain lidocaine or certain other local anaesthetics (of the amide type) because this may result in a non-foreseeable mutual intensification of their effects.

Because of the possibly increased effect on the heart, lidocaine should be used cautiously on patients who take medicines for the treatment of arrhythmias (antiarrhythmics) such as mexiletine, tocainide, beta blockers such as propranolol or calcium channel blockers (e.g. diltiazem, verapamil) at the same time.

No specific drug interaction studies were carried out for lidocaine and class III antiarrhythmics (e.g. amiodarone), but caution should be exercised (see also "Special caution is required for the use of Cathejell") because the effects on the heart could increase.

If you take cimetidine (inhibits the production of stomach acid), talk to your doctor before using Cathejell. The concomitant use of such medicines (H<sub>2</sub> blockers) can increase the risk of lidocaine side effects.

### **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 or a healthcare professional for advice before using this medicinal product.

During pregnancy and when breastfeeding, Cathejell should only be used after a careful benefit/risk analysis by your doctor and after the dose was determined on an individual basis. Repeated use during pregnancy and when breastfeeding is not recommended.

Please note that a time interval of 12 hours between the use of Cathejell and subsequent breastfeeding is recommended.

### **Driving and using machines**

Cathejell has no or negligible influence on the ability to drive and use machines. However, an influence on the ability to drive and to use machines cannot be excluded completely in the event of increased personal sensitivity.

## **3. How to use Cathejell**

It is applied exclusively by a doctor or a healthcare professional.

The dose is adjusted individually.

The following dosage information serves as a guideline, the doctor's experience and the knowledge of the patient's physical state are important for the calculation of the suitable dosage.

The extent of absorption is especially high in the bronchial tree.

### **Application in the urethra before introducing a catheter, endoscope or other medical instruments**

The collapsible syringes (hereinafter referred to as "syringes") contain 12.5 g or 8.5 g gel each, of which approx. 10 g or 6 g are introduced in the urethra during introduction (instillation).

### ***Posology***

#### **Adult males:**

In general, the 12.5 g syringes are required for men in order to fill the urethra sufficiently. The content of a syringe is enough, more than one syringe should not be used. The effect sets in after 5 - 10 minutes and continues for approx. 20-30 minutes.

#### **Women, children (aged 2 - 12 years) and adolescents (under 18 years of age):**

The effect of Cathejell is not documented that well, therefore a doctor should decide whether it is necessary to use it.

For these groups of patients, no specific dosage recommendations can be given, but in general, the quantity of gel to be introduced is to be adapted to the individual, anatomic conditions of the urethra.

In children, the absorption of lidocaine through the mucous membranes in the organism may be increased, and so caution should be exercised. The maximum dose of 2.9 mg/kg BW lidocaine hydrochloride should not be exceeded in children (aged 2 - 12 years).

#### **Children under 2 years of age:**

Cathejell must not be used on children under the age of 2 years.

*Dosage recommendations for high-risk patients:*

In elderly, weak or acutely sick patients as well as patients with impaired liver function or severe renal dysfunction, the dosage is to be adjusted accordingly. The maximum dosage 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 orifice of the urethra
2. Peel off the paper from the transparent cover up to the waist of the blister pack
3. Break off the tip, still in the blister pack if required
4. Completely remove tip to prevent inadvertent insertion in the urethra
5. Squeeze out one drop of gel for easier insertion of the applicator cone
6. Slowly instill the gel by applying steady pressure to the syringe.

Single-use product, dispose of gel residue from syringes that were not emptied completely.

*Use for general anaesthesia and tracheal intubation*

***Posology***

*Adults and adolescents (aged > 12 years):*

Evenly distribute approx. 5 g across the bottom third of the tube (the hollow needle). In order to prevent drying out, the gel is only applied to the instrument immediately before administration. Do not get any gel into the lumen of the tube. The maximum dose is 16 g Cathejell for adults with a normal body weight.

*Children (aged 2 - 12 years):*

In children, the absorption of lidocaine through the mucous membranes in the organism may be increased, and so caution should be exercised. The maximum dose of 2.9 mg/kg BW lidocaine hydrochloride should not be exceeded in children (aged 2 - 12 years).

*Children under 2 years of age*

Cathejell must not be used on children under the age of 2 years.

*Dosage recommendations for high-risk patients:*

In elderly, weak or acutely sick patients as well as patients with impaired liver function or severe renal dysfunction, the dosage is to be adjusted accordingly. The maximum dosage must be calculated in mg lidocaine hydrochloride/kg body weight (2.9 mg lidocaine hydrochloride/kg BW).

***Method of administration***

For application to tubes, endoscopes and tracheal tubes.

Single-use product, dispose of gel residue from syringes that were not emptied completely.

**If a larger quantity of Cathejell was used than prescribed**

If you notice signs of an overdose, immediately see a doctor or go to a hospital.

It is applied by a doctor or a healthcare professional, which is why an overdose is unlikely.

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In the event of an overdose in spite of that, e.g. if the quantity of gel applied was not optimally adjusted to the patient, if a considerable quantity gets in the urinary bladder, or if the mucous membrane is ulcerous or injured, that may result in an increased absorption of lidocaine and subsequently overdosage involving disturbances of the central nervous system and the cardiovascular system. This applies in particular if other local anaesthetics were used at the same time.

On overdose causes disturbances of the central nervous system. First signs of an overdose may be central nervous agitation with anxiety, dizziness, trembling, impaired hearing and vision, numbness of the tongue and the lips or nystagmus. There may also be excitation of the cardiovascular system with increased heart rate, increased blood pressure and redness of the skin.

Higher doses cause drowsiness and twilight sleep (sedation), chills, twitching muscles and cramps.

Side effects involving the cardiovascular system, such as drop in blood pressure, slowed heart rate or cardiac insufficiency, usually only occur with very high blood concentrations of lidocaine.

A massive overdose of lidocaine can cause respiratory paralysis and cardiac or circulatory failure.

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*Information for healthcare professionals: For more information about overdosage, refer to the end of this package leaflet.*

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If you have further questions regarding the use of this medicinal product, ask your doctor or a healthcare professional.

#### **4. Possible side effects**

Like all medicinal products, this medicinal product can cause side effects, although not everybody gets them.

Side effects after an application of Cathejell are rare if the product is used according to the recommendations for dosage and application and in compliance with the necessary precautions (see section 2.).

The development of side effects is mostly due to accelerated absorption (from the site of application into the bloodstream), overdosage or hypersensitivity.

##### ***Rare (may affect up to 1 in every 1000 patients)***

Allergic reactions such as respiratory distress caused by a constriction of the airways (bronchospasm), general respiratory distress (respiratory distress syndrome), allergic skin reactions such as redness, stinging or pruritus, urticaria, swelling of tissue (oedema).

##### ***Unknown (frequency not assessable based on the available data)***

Allergic reaction concomitant with drop in blood pressure, dizziness, nausea, vomiting, respiratory distress and unconsciousness (anaphylactic shock); nervousness/anxiety, dizziness, shaking, drowsiness, unconsciousness, convulsions, disorientation, impaired speech, bleary look, dilation of the pupils, low blood pressure, slowed heartbeat, cardiac arrest, cardiac arrhythmias, rise in blood pressure, rise in heart rate, respiratory arrest, vomiting, muscle twitching, irritation of pharynx, hoarseness (when applied as lubricant for the breathing hose through the windpipe), irritation at the site where the gel is applied (application site).

##### **Reporting of side effects**

If you get any side effects, talk to your doctor or a healthcare professional. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen  
Traisengasse 5  
1200 VIENNA  
AUSTRIA  
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

Store this medicinal product in the original packaging (blister in carton) to protect the contents from light.

Keep this medicinal product out of the reach of children.

Do not use this medicinal product after the expiry date which is stated on the carton/blister pack/label after "Use before:"/"Use bef.:". The expiry date refers to the last day of that month.

Cathejell collapsible syringes are intended for single use, dispose of gel residue from syringes that were not emptied completely.

Do not throw away any medicinal products via waste water or household waste. The medicinal product will be disposed of by healthcare professionals when it is no longer used. These measure is a contribution to environmental protection.

## 6. Contents of the pack and other information

### What Cathejell contains

- *The active substance is:* lidocaine hydrochloride  
1 g gel contains 20 mg lidocaine hydrochloride.
- *The other ingredients are:* hydroxyethyl cellulose, glycerol, water for injection, sodium hydroxide solution and hydrochloric acid solution for adjusting the pH level.

### What Cathejell looks like and contents of the pack

Colourless and clear, water-soluble gel.

Sterile single-use product.

The gel is filled in collapsible syringes containing 8.5 g or 12.5 g each. The individual syringes are packed in blister packs and steam sterilised. The blister packs are packed in cartons.

25 collapsible syringes containing 8.5 g gel each in carton

25 collapsible syringes containing 12.5 g gel each in carton

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The following information is intended for healthcare professionals:

### **Overdosage emergency measures**

The treatment of an intoxication involving the CNS (convulsions, CNS depression) or the cardiovascular system is symptomatic, e.g. by administering anticonvulsants, and/or supporting cardiopulmonary emergency measures:

- Immediately stop the supply of lidocaine
- Maintain the airways
- Supply oxygen until all vital functions are back to normal
- Check blood pressure, pulse and dilation of pupils.

### **Possible further countermeasures**

In the event of an acute, dangerous drop in blood pressure, elevation of legs and slow i.v. injection of a beta sympathomimetic and additional volume substitution.

In the event of an elevated vagal tone (bradycardia), atropine is administered.

Convulsions that persist for longer than 30 seconds are treated by administering an anticonvulsant (e.g. diazepam).

Persistent convulsions can be controlled by injecting a muscle relaxant (e.g. suxamethonium).