PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

CATHEJELL WITH LIDOCAINE

Gel for Urethral Instillation

Composition:
Active ingredients and their concentrations:
Lidocaine hydrochloride 2%
Chlorhexidine dihydrochloride 0.05%

For the list of inactive ingredients, refer to section 6 at the end of this leaflet.

Read all of this leaflet carefully to the end before you start using this medicine. This leaflet contains concise information about the medicine.
If you have any further questions, refer to the doctor or pharmacist or nurse.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

1. What is the medicine used for?

This medicine is intended for local anesthesia when used for instillation into the urethra prior to the insertion of a catheter or other device.
Therapeutic group: Lidocaine - local anesthetic agent; chlorhexidine - local antiseptic agent.

Mechanism of action of the drug:
Cathejell with Lidocaine is a sterile, anaesthetising gel.

Besides its lubricant action, it has a local anaesthetic and germ-killing effect to relieve pain during medical procedures and prevent infections to a large extent. The effect sets in as early as 5 to 10 minutes after application and lasts for 20 to 30 minutes.

As a local numbing agent (local anaesthetic), it contains lidocaine. In topical anaesthesia, it generally takes effect after about 3 to 5 minutes. In inflamed tissue, the effect is reduced.

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

2. Before using the medicine

Do not use Cathejell with Lidocaine:

- if you are sensitive (allergic) to the active ingredients or to any of the additional ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to certain other local anaesthetics (of the amide type)
- in children under 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 very poor heart function, markedly 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.

Special warnings regarding use of the medicine:

Before using Cathejell with Lidocaine, inform your doctor:

- if used frequently and at high doses, as this may lead to severe side effects.
- 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 (epilepsy).
- if you are suffering from a certain muscle disease (myasthenia gravis).
- if you are being treated with certain medicines for 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).
- if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

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 inflamed/ulcerous, 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 are given more than you should").

Cathejell with Lidocaine must not come into contact with the eyes.

Under general anaesthesia, a lubricant without lidocaine should be preferred.

Drug interactions:

- If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

- Cathejell with Lidocaine 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 medicines 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 "Warnings and Precautions"), 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 with Lidocaine. Using such medicines at the same time can increase the risk of 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 nurse for advice before using this medicine.

During pregnancy and breast-feeding, Cathejell with Lidocaine 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 with Lidocaine and subsequent breast-feeding.

Driving and using machines

Cathejell with Lidocaine has no or negligible influence on the ability to drive or use machines. However, effects on the ability to drive and use machines cannot be ruled out entirely in the case of increased individual sensitivity.

3. How to use the medicine

Always use this medicine according to the doctor's instructions.
Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine.

The dosage and the method of treatment will be determined by the doctor only. The usual dosage is: 1 syringe. Never instil more than one syringe (see "Directions for use").

Attention!
Do not swallow! This medicine is intended for external use only.
Avoid contact with the eyes.
Do not exceed the recommended dose.

Directions for use:
Use in the urethra before inserting a catheter, endoscope or other medical instruments.
The accordion syringes (hereafter called 'syringes') contain 12.5 g gel, of which approximately 10 g are inserted into the urethra during instillation.
The amount of gel to be instilled depends on the anatomical conditions of the urethra.

Slow instillation of the gel into the urethra prior to the insertion of a medical device. **The treatment will be performed by a physician or other qualified personnel only.**
1. Clean the external orifice of the urethra.
2. Peel off the paper from the blister back cover and break off the applicator tip.
3. Release one drop of gel for easier insertion of the applicator.
4. Apply gradual pressure to instil the content of the accordion syringe.

Intended for single use. Discard any remaining gel in partially empty syringes.

If you accidentally took a higher dose than you should

If signs of overdose occur, contact a doctor or hospital immediately.

As this medicine is administered by a doctor or healthcare professional, an overdose is unlikely.

However, if an overdose should nevertheless occur, e.g. if the amount of gel used has not been optimally adjusted to the patient, if a large amount of gel gets into the bladder, or if the mucous membranes are inflamed, ulcerous or injured, this can lead to increased absorption of lidocaine and result in disturbances of the central nervous system or cardiovascular system. This applies particularly 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, lightheadedness, sleepiness and trembling. First signs of an overdose may be numbness of the tongue, involuntary eye movements, lightheadedness 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 of lidocaine.

If you have taken an overdose or if a child has accidentally swallowed this medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Note to healthcare professionals: More information on overdose is provided at the end of this leaflet.

The treatment should be continued as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.

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

4. Possible side effects:

Like all medicines, use of Cathejell with Lidocaine may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects may occur:

Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1 000 to 1/1,00)
Rare	(≥1/10 000 to <1/1 000)
Very rare	(<1/10 000)
Not known	(frequency cannot be estimated from the available data).

Side effects rarely occur after the use of Cathejell with Lidocaine, provided that the product is used according to 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, lightheadedness, blurred vision or trembling, sleepiness, unconsciousness and respiratory arrest, drop in blood pressure, slow heart rate, cardiac arrest. For treatment of side effects, see section 3 “If you accidentally took a higher dose than you should”.

General disorders and administration site conditions

Only low lidocaine blood levels are likely when used in urology; other systemic side effects after instillation of Cathejell with Lidocaine into the urethra are therefore normally not expected to occur.

Immune system disorders

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

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult a doctor.

Reporting of side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" located on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il.

5. How should the medicine be stored?

- Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
  Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

- Store at a temperature below 25°C. Store in the carton box in order to protect from light.
- Intended for single use. Discard any remaining gel in partially empty syringes.
- Do not throw away any medicines via wastewater or household waste. This medicine will be discarded by healthcare professionals when no longer needed. These measures will help protect the environment.

6. Further information

In addition to the active ingredients, the medicine contains:
hydroxyethyl cellulose, glycerol, sodium lactate solution, water for injections, sodium hydroxide solution and hydrochloric acid solution for pH adjustment.

What the medicine looks like and contents of the package:
Water-soluble and clear, colourless gel.
Sterile single-use form.
The gel comes in accordion syringes with 12.5 g. The individual syringes are packed in blisters and steam-sterilised. The blisters are packed into cartons.

25 accordion syringes with 12.5 g gel in a carton.

Registration Holder and address:
A.Lapidot Pharmaceuticals Ltd.,
8 Hashita Street, Industrial Park Caesarea 3088900.

Manufacturer and address:
Pharmazeutische Fabrik Montavit GmbH, Salzberstrasse 96, A-6067 Absam, Austria

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
134-65-31156-00

The following information is intended for 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 discontinuation 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 interventions

For acute life-threatening hypotension, elevation of the legs and slow IV injection of a beta-sympathomimetic (e.g. 10 to 20 drops per minute of a 1 mg isoprenaline solution in 200 mL glucose solution 5%) and additional volume replacement.

In case of increased vagal tone (bradycardia), 0.5 to 1 mg atropine is administered IV.

Convulsions lasting for more than 30 seconds are treated by administering an anticonvulsant (thiopental sodium 1 to 3 mg/kg IV or diazepam 0.1 mg/kg BW IV).

Persistent convulsions can be controlled by injecting a muscle relaxant (e.g. succinylcholine (suxamethonium) 1 mg/kg BW).

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