CATHEJELL WITH LIDOCAINE
PYSICIAN'S LEAFLET

NAME OF PRODUCT

Cathejell with Lidocaine

QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine hydrochloride 2% w/w
Chlorhexidine dihydrochloride 0.05% w/w
For excipients see section *"LIST OF EXCIPIENTS"*

PHARMACEUTICAL FORM

Sterile, anesthetizing and antiseptic, water-soluble, colourless, clear gel for intraurethral instillation.

Sterile single administration form.

THERAPEUTIC INDICATIONS

Instillation into the urethra prior to the instillation of a catheter or other instruments (catheterization, cystoscopy) and manipulations which require the use of a local anesthetic.

POSOLOGY AND METHOD OF ADMINISTRATION

Cathejell with Lidocaine is instilled into the urethra prior to the insertion of instruments and/or applicated onto the instrument.

The content of one syringe is sufficient to fill the urethra.
Never instil more than one syringe.

The tubes contain 12,5 g, of which 10 g are instilled into the urethra.

Slow instillation of the gel into the urethra prior to the insertion of instruments (by a physician or trained medical qualified personnel).

Handling:

1. Clean and disinfect the external orifice of the urethra.
2. Peel off the paper from the blister back cover (possibly up to the waist of the transparent blister material).

3. Break off the applicator tip (in the blister pack if required).
Take care to remove the tip completely to prevent insertion into the urethra.
4. Release one drop of gel for easier insertion of the applicator.
5. Complete extrusion by applying slight steady pressure to the accordion

The duration of application is not limited.

CONTRA-INDICATIONS

Cathejell with Lidocaine should not be used in patients with hypersensitivity to any of the components or patients with marked bradycardial rhythm disorders.

Do not press into the urethra after a failed catheterisation (possibly apply the gel to the instrument or aspirate urine suprapubically).

Cathejell with Lidocaine should be used with caution in patients with severe cardiac insufficiency, seriously impaired hepatic and renal function, traumatized mucosa and/or inflammation/sepsis in the region of the proposed application and in patients with tendency to convulsions (epilepsy, severe shocks).

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Under anesthesia a lubricant without lidocaine should be used.

Instillation should only be performed by a physician or by qualified medical personnel.

Patients with glucose-6-phosphate dehydrogenase deficiency or congential or idiopathic methaemoglobinaemia are more susceptible to drug induced methaemoglobinaemia. Do not use in children under one year of age who are receiving methaemoglobinaemia inducing drugs.

Do not use in premature infants who were born before 37 weeks of gestation.

DRUG INTERACTIONS

Lidocaine should be used with caution in patients receiving antiarrhythmic drugs, ß-receptor blocking agents or calcium channel antagonists because of the possible additive inhibition on the cardiac P-Q transition, intraventricular excitation conducting and contractility.

PREGNANCY AND LACTATION
Cathejell with Lidocaine can be used during pregnancy and lactation, the risk/benefit assessment should be decided by the physician.

Lidocaine passes the placenta and enters breast milk in small quantities; however, there is generally no risk to the foetus and infants at the therapeutic dose level used in Cathejell with Lidocaine.

SIDE EFFECTS

Allergic reactions to lidocaine and chlorhexidine are extremely rare.

In the case of hypersensitivity skin reactions are possible.

Systemic adverse reactions to lidocaine are rare and may result from hypersensitivity or diminished tolerance.

From the technique and duration of the application and from the lidocaine concentration systemic adverse reactions generally are not expected.

Application of more than one tube whereas jelly enters into the bladder or severe inflammation of the urethra resulting in an increase of lidocaine absorption may lead to an overdose with systemic central nervous and cardiovascular reactions.

Central nervous system reactions are excitatory and/or depressant and may be manifested by prodomal symptoms such as nervousness, dizziness, vertigo, somnolence, tremor.

Cardiovascular reactions, characterized by bradycardia, myocardial depression and increase of ventricular activation time usually only occur at very high blood concentrations of lidocaine.

OVERDOSE

a) Symptoms of an intoxication with lidocaine (blood concentration: >5 µg/ml) are characterized by beginning prodomal symptoms such as nervousness, dizziness, vertigo, somnolence and in more serious cases loss of consciousness, respiratory depression and cardiac arrest. More symptoms are: visual disorders, tinnitus, vomiting.

b) Therapy of an intoxication:
In common with other anaesthetic/antiseptic gels, treatment of a patient with systemic toxicity consists of ensuring adequate ventilation with oxygen, if necessary by assisted or controlled ventilation. If convulsions do occur, they could be treated rapidly by intravenous injections of Diazepam 5 to 15 mg. Necessity of circulation assisting manipulations depends on the clinical symptoms. If bradycardia or cardiac arrest occurs atropin or sympathomimetica (adrenalin) should be given intravenously as soon as possible and cardiovascular resuscitation performed.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Cathejell with Lidocaine is a sterile, anesthesizing and antiseptic gel for urethral instillation. The combination of the two active ingredients lidocaine hydrochloride and chlorhexidine dihydrochloride has been employed for many years and has been shown to be effective and without significant adverse reactions.

Lidocaine is an aminoethylamide, with a fast, intense and long-lasting anesthetic effect, beginning 3 to 5 minutes after application and lasting 30 to 50 minutes. Apart from its anesthetic effect, lidocaine is also used as an antiarrhythmic agent.
Cathejell with Lidocaine causes a topical surface anesthesia.

Chlorhexidine is an antimicrobial, potent against many gram-positive and -negative bacteria but is ineffective against acid-resistant bacteria, spores, fungi and viruses. In the concentration presented it is a prophylactic against iatrogenic infections of the upper urethra and bladder.

Pharmacokinetic properties

Lidocaine is absorbed from mucus membranes: Following a high dose application to the mucosa with a long dwelling time maximum blood concentration was 1,2 µg/ml, indicating that plasma levels are below the levels at which systemic effects or toxicity are likely to occur. In the case of severe inflammatory processes of the urethral mucosa an increase of lidocaine resorption has to be expected.
Blood concentration following intravenous administration as antiarrhythmic is 1 to 6 µg/ml.

Plasma protein-bounding: 40% (40 to 80%). Plasma half-life: 1 to 2 hours.

About 95% of lidocaine in the liver is metabolized, 5% is excreted in the urine. Hepatic insufficiency decreases lidocaine degradation to 1/10 of standard value. Renal insufficiency possibly is followed by accumulation of active metabolites.

Absorption of chlorhexidine is extremely low after local application.

LIST OF EXCIPIENTS

The excipients used in Cathejell with Lidocaine are hydroxyethylcellulose, glycerol, Sodium lactate solution and water for injections.

SHELF-LIFE

Three years from the date of manufacture.

After incomplete withdrawal remove the residual gel. Do not use after expiration date.

STORAGE

Store at room temperature (up to 25°C) within the original carton and protect from light.

CONTENTS OF CONTAINER

Cathejell with Lidocaine gel is contained in polypropylene collapsible tubes (accordion syringes) with an applicator cone and a break-off rod.
Individual tubes are packed in blisters, consisting of steam-sterilizable polypropylene thermofoil with paper backing (medical sterile paper).

Blister strips are stored in cartons, containing 25 single syringes.

INSTRUCTIONS FOR USE/HANDLING

Cathejell with Lidocaine syringes are for single use only, remove the residual gel.

MANUFACTURER

Pharm Fabrik Montavit GmbH, Austria

REGISTRATION HOLDER

A.Lapidot Pharmaceuticals Ltd., 8 Hashita Street, Industrial Park Caesaria 38900.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in May 2011.