PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS REGULATIONS (PREPARATIONS) – 1986
The medicine is marketed by prescription only
Read this package insert carefully in its entirety before using this medicine

CATHEJELL WITH LIDOCAINE

Gel for Urethral Instillation

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

Inactive ingredients:
Hydroxyethylcellulose, Glycerol, Sodium lactate solution, -Water for injection.

Therapeutic group:
Lidocaine - local anesthetic agent; chlorhexidine - local antiseptic agent.

Indication:
This medicine is intended for instillation into the urethra prior to the insertion of a catheter or other medical device, endoscopy, cystoscopy.

When should the preparation not be used?

Do not use this medicine if you are sensitive to any of its ingredients or if you suffer from severe bradycardia (slowing of heart rate).
Do not use this medicine in infants under one year of age receiving methaemoglobinaemia-inducing medicines such as sulfonamides.
Do not use this medicine in premature babies born at less than 37 weeks gestational age.
Do not use in cases of wounded or inflamed skin in the area of application.
Do not instill the gel directly into the urethra after unsuccessful attempt of catheter insertion.

Do not take this medicine without consulting a doctor before starting treatment:
If you are pregnant or breast-feeding.
If you have a deficiency of the G6PD enzyme (sensitivity to fava beans).
If you suffer or have suffered in the past from impaired function of the heart, the blood system (e.g. anemia), the liver, the kidney or epilepsy.

Warnings:
This medicine may cause local sensitivity.
Under anesthesia, a lubricant without lidocaine should be used.

Drug interactions:
If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: other local anesthetic agent, sulfonamides and medicines for the treatment of arrhythmias.

Side effects:
In addition to the desired effect of the medicine, during the course of treatment adverse reactions may occur, for example: local irritation, sense of heat, allergic reaction.
In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Dosage:
Recommended dosage unless otherwise prescribed by your doctor:
1 accordion Syringe. Never instill more than one accordion syringe (see "Directions for use").

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

Directions for use:
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 instill the content of the accordion syringe.

Avoid poisoning!
This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.
If a child has accidentally swallowed this medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
Do not induce vomiting unless explicitly instructed to do so by a doctor!

Storage:
Store at a temperature below 25^{o}C Store in the carton box in order to protect from light.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package.

Drug registration number: 134 65 31156 00

Manufacturer: Pharm Fabrik Montavit GmbH, Austria.

Registration Holder: A.Lapidot Pharmaceuticals Ltd., 8 Hashita Street, Industrial Park Caesarea 38900.

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