KONIX LIDO e STERiL KATETER JEL KULLANIM KILAVUZU / *INSTRUCTION FOR USE OF KONIX LIDO e STERILE CATHETER GEL*

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PROOUCT NAME: Konix Lido C Sterile Catheter Gel

DESCRIPTION: Konix Udo e Sterile Catheter Gel is a sterile \Nater soluble, non-irritatlng lubricant gel with supportrve antiseptic and anesthetic properties used to facilitate the in.sertion of catheters and other medicai instruments (catheterization, cystoscopy) intothe urethra and bladder.

It helps preventing trauma, which may occur during the catheterization between the urethral mucoS3 and catheter, by lubricating effect. It reduces infection risk by antiseptic property of chlorhexidine and helps reducing perioperative pain associateci with the procedure by locai anesthetic property of lidocaine. It minimizes patient discomfort caused by procedure.

INCREOIENT: 100 g of Konix Udo e Sterile catheter Gel contains;

Deionized Water, Hydroxyethyl Cellulose (Lubricative), Mono Propylene Glycol (Moisturizer),2g Lidocaine (Locai anesthetic),0.05 g Chlorhexidine Gluconate {Anti.septic), Metll),'1 Hydroxybenzoate (Preservative), Propyl Hydroxybenzoate (Preservative)

APPLICATION:

1 wash your handsand prepare an area that is aseptic as possibleto performthe operation. Prepare a clean serving trayand piace required materials.

2 Removethesyringe (6 ml,72 ml and725g) from itssterile package bytearing off. 6 ml syringe issuitablefor use in women and children, while '2 ml S)'finge and 125 g accordion sylinge are suitable far use in men.

3 Lightly press on the plunger before removing the blue cap to provide more even and gentle application. Far the accordion syringe, breakofftheapplicatortip.

4 Carefully insertthe eone ofthe syringe into the urethral opening and slavvly inject the gel by applying gentle and even pressure.

S.Applythe remaining gel tothesurface ofthecatheterortothesurface ofanother medicai device.

6 Konix Lido e Sterile catheter Gel shCNS lubricative effect assoon astlle application starts. Itsanesthetic effectstarts3-5 minutes later.

7. Ifmore gel has to be used, condition ofthe applied tissue, age ofthe patient and any adverse condition ofthe patient which maybe relatedtoser\Sitivit;yofchlorhexidine mLJSt betaken intocare bythe physician.

B When the whole product is not used, the syringe and the remaining gel should be evaluated and discarded like other medicai wastes.

9 Konix Udo C Sterile Catheter Gel should only be used under the supervision of specialist health personnel.

CONTRAINOICATIONS: Konix Lido e Sterile catheter Gel should not be used in patients with hypersensitivity to any of the components or patients with marked bradycardial rhythm disorders. Konix Lido e Sterile Catheter Gel should not be used in patientswith severe cardiac insufficiency, severe hepatic and renai dy.;function, traumatic mucosa and / or inflammation / .sepsis atthe application site, and in patients with a tendencyto convulsion (epilepsy; severe shocks). Do not use in children under 2years

WARNINCISAND PRECAUTIONS FOA USE

• Underanesthesia a lubricantwithout lidocaineshould be used.

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

, Patients with glucose-6-phospate dehydrogenase deficiency or congenital or idiopathic methaemoglobinaemia are more susceptibleto drug induced methaemiglobinaemia.

-When applying Konix Lido e Sterile Catheter Gel, a temporary burn may occur; patients should be warned in this regard. Ih this case, cold compress to the applied region can alleviate the burning sensation.

-Allergie reactionsto lidocaineand / or chlorhexidine mayrarelyoccur. Please consultyour doctor if redness, burning and stinging occurs in the applied site.

• Irritateseyesand/or skin in caseof directcontact. Washwith plentyofwater in caseofexposure.

• If swallowed, seek medicai advice.

• KeepcNi1ayfrom children.

•Stare in dryand cool places.

, KeepcNiléfffrom directsunlight.

• Forsingle useonly.

• Do not re-sterilize.

- Do not use productswith damaged packages because ofthe risk ofsterilization deterioration.

PRECNANCY **ANO LACTATION:** Konix Lido C Sterile Catheter Gel can be used during pregnancy and lactation. The risk/benefit assessment should be performed by the physician. Udocaine passes to placenta and enters breast milk in small quantities; however, therapeutic dose used in Konix Lido e Sterile Gatheter Gel does not generally pose a riskto the fetus and infants.

DRUCi INTERACTION

, Interaction due to absorption of lidocaine may occur when used in combination with the follavving drugs;

Propranolol: Reduction in plasma clearance of lidocaine

Cimetidine: Reduction in plasma clearanceof lidocaine

Antiarrhythmic products: Increase in toxicityof lidocaine

Phenytoin or barbiturates: Reduction in plasma levelsof lidocaine

The specified interactionscan be seen in long-term use and repeated high doses. No dinically significant interactions hsAel been reported when administered at the recommended doses.

• Due to the risk ofinteraction depending on chlorhexidine, use with the follovving is not recommended;

Chlorhexidine Gluconate (CHX) + Sodium Hypochlorite (NaOCl)

Chlorhexidine Gluconate (CHX) + Hydrogen Peroxide (H202)

Chlorhexidine Gluconate (CHX) + Povidone-Iodine (BTD)

According to scientific literatures. CHX + NaOCl interaction is known to produce toxic by-products far humans.

SIDE EFFECTS: Allergie reactions to lidocaine and chlorhexidine are extremely rare. In the case of hypersensitivity, skin reactions are possible, Skin reactions depending on anaphylaxis (hypersensitivity) may occur due to the use of lidocaine in the damaged mucosa.Systemic adverse reactionsto lidocaineare rareand mayresuttfrom hypersensitivityordiminishedtolerance.

PACKACINC

- Konix Lido C Sterile CatheterGel issupplied as sterile in disposable packages, prefilled in 6 ml (4 6 g), 12 ml (4 12g] syringes and 125 g accordion syringe.

- Konix Lido e Sterile Catheter Gel 6 ml (25 x 6 ml / Box]

, Konix Lido e SterileCatheterGell2 ml (2Sxl2 ml/Box)

• Konix Lido C Sterile Catheter Gel 125 g (25 xl25 g / Box)

STERILIZATION: Konix Lido e Sterile catheter Gel issterilize<:l with radiation after the packaging. In case the package damaged, do not use since it will lose the steriity.

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KONIX®

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PROSPEKTUS/IFU

Tarih: 27I 10 I 2021

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ORONISMI	: KONIX 6·12 ML STERIL KATETER LIDO C JEL ORTAK PROSPEICI'US • VENI **ADRES**		
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