CATHETER GEL

KATETER JEL / GEL POUR CATHÉTER / GEL DE CATÉTER

107.0007
12 ml.

STERILE R

107.0005
6 ml.

107.0015
12,5 gr.

EN Properties & Use

Konix Sterile Catheter Gel is a sterile lidocaine contained, clear and water-soluble sort of gel which is used before applying cathether, cystoscopy and/or else medical instrument to urethra. Covering urethra by generating a slick layer between urethral mucosa and catheter or else medical instrument is the most significant function of the gel. Catheter Gel, including Lidocaine, inside, is used before the application in order to replace urethra for the purpose of dulling the pain related to urethral manipulation. Moreover, it provides an indolent catheterization with its anaesthetic effect. Antiseptic effect of the gel insulates patients from the potential infections that may occur within the upper part and urinary bladder due to iatrogenic contamination.

Storage: Store in a cool and dry environment between 5 – 30 °C away from direct sunlight.

FR Propriétés & Utilisation

Cahéter stérile est une lidocaïne stérile contenant du gel clair et soluble dans l'eau qui est utilisé avant l'application de cathéter ou d'autres instruments médicaux sur l'urètre, pour des examens cystoscopiques ou autres. Recouvrir l'urètre en générant une couche lisse entre la muqueuse urétrale et le cathéter ou d'autres instruments médicaux c'est est la plus importante fonction du gel. Konix Gel pour cathéter stérile comprenant de lidocaïne, est utilisé avant l'intervention afin de protéger l'urètre pour atténuer la douleur liée à la manipulation urétrale. En outre, la pose du cathéter devient indolore grâce à son effet anesthésique. L'effet antiseptique du gel protège les patients d'une infection éventuelle qui pourrait se déclarer dans la partie supérieure et de la vessie et due à la contamination iatrogène.

Stockage: Conserver dans un endroit frais et sec entre 5 - 30 ° C à l'abri des rayons soleil.

TR Özellikler & Kullanım Şekli

Lidokain içeren Konix Steril Kateter Jeli, üretraya kateter, sistoskopi ve/veya başka bir tıbbi alet uygulamadan önce kullanılan steril, berrak, suda çözünen kaydırıcı bir jeldir. Jelin en önemli fonksiyonu kateter veya başka bir tıbbi alet ile üretral mukoza arasında kaydırıcı bir tabaka oluşturarak üretrayı kaplamasıdır. Lidokain içeren Konix Steril Kateter Jelin uygulamasından önce üretral manipulasyonla bağlantılı olan ağrının giderilmesinde yardımcı olmak amacıyla üretranın kaydırılması için kullanılır. Ayrıca anestezik etkisi ile ağrısız bir kateterizasyon sağlar. Konix Steril Kateter Jeli'nin antiseptik etkisi iatrojenik kontaminasyondan dolayı üst bölümü ve mesanede oluşabilecek enfeksiyonlardan hastayı korur.

Saklama Koşulları: 5-30°C'nin arasında ve güneş ışığından uzakta, serin bir yerde muhafaza ediniz.

ES Características y Modo de Empleo

Catéter contiene lidocaína y es un gel lubricante de tipo estéril, transparente y soluble en agua, que se utiliza antes de aplicar el catéter, la cistoscopia y/o otro dispositivo médico a la uretra. La función más significativa del gel es cubrir la uretra mediante la generación de una capa resbaladiza entre la mucosa de la uretra y el catéter u otro dispositivo médico. Konix Gel Estéril de Catéter que contiene lidocaína se utiliza antes, para remplazar la uretra con el fin de evitar el dolor relacionado con la su manipulación. Además, proporciona un cateterismo indolente gracias a su efecto anestésico. El efecto antiséptico de Konix Gel Estéril de Catéter protege a los pacientes de las posibles infecciones que pueden originarse dentro de la parte superior de la vejiga y que es debida a la contaminación iatrogénica.

Almacenamiento: Conservar en ambiente seco y fresco entre 5-30° C fuera del alcance directo de la luz solar.

ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV

ELECTROTECHNICAL TESTING INSTITUTE - CZECH REPUBLIC
ELEKTROTECHNISCHE PRÜFANSTALT - TSCHECHISCHE REPUBLIK
INSTITUT ELECTROTECHNIQUE D'ESSAIS - RÉPUBLIQUE TCHÈQUE
[illegible]

Pod Lisem 129, 171 02 Praha 8 - Troja

EC CERTIFICATE
FULL QUALITY ASSURANCE SYSTEM

issued in accordance with Annex 2 of Government Order No. 54/2015 Coll.
(Annex II of Directive 93/42/EEC)

No.: MED 170030

The Electrotechnical Testing Institute, Notified Body No. 1014, on the basis of the carried out audit results has decided that the quality system established at the

manufacturer **TURKUAZSAĞLIK HİZMETLERİ MEDİKAL TEMİZLİK KİMYASAL ÜRÜNLERİSAN.VE TİC, LTD. ŞTİ.**
Yakuplu Mah. Birlik Cad No:34/3 Beylikdüzü, İstanbul, Turkey

for design, manufacturing and final inspection of medical device(s)

Catheter gel with lidocain - class III

meets the provisions of Annex 2 of Government Order No. 54/2015 Coll., which specifies technical requirements for medical devices (Annex II of Directive 93/42/EEC). The certificate does not cover examination of the medical device design in accordance with Annex 2 clause 8 of Government Order No. 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

The notified body agrees with attaching its identification number 1014 to CE marking, which will be affixed to the above mentioned medical device(s) in accordance with Article 6 of Government Order No. 54/2015 Coll. (clause 17 of Directive 93/42/EEC).

The decision was based on the results presented in the audit report No. **203303-01 of 30.5.2017**.

The approved quality system established at the manufacturer is subject to regular surveillance audits by the notified body in accordance with Annex 2 clause 11 of Government Order No. 54/2015 Coll. (Annex II clause 5 of Directive 93/42/EEC). The manufacturer must inform the notified body which approved the quality system about any intention of substantial changes to the quality system or the product range covered. In case that the conditions under which the certificate has been issued are violated, the notified body may suspend the validity of the certificate or cancel the certificate.

For class III medical devices this certificate can be used only with EC Design Examination Certificate issued in accordance with Annex 2 clause 8 of Government Order 54/2015 Coll. (Annex II clause 4 of Directive 93/42/EEC).

Edition 1

The first issue of this Certificate from 05.06.2017 with validity until 04.06.2022.
The validity of this Certificate is limited until: 04.06.2022

05.06.2017

Prague

Mgr. Miroslav Sedláček
Head of Certification Body

Stamp

203303-01