

Uro-Tainer® PHMB

0.02 % Polihexanide

PVC-free

Maintenance solution for urethral and suprapubic catheters
Sterile, non-pyrogenic

Composition
100 ml solution contain:
polyhexamethylene biguanide (polihexanide, PHMB) 0.02 g
Sorbitol 5.0 g
in Water for Injections

Description
A solution for the maintenance of indwelling urethral and suprapubic catheters to aid removal of deposits, tissue waste, clots, and mucous. Uro-Tainer® Polihexanide 0.02%, supported by the preservative property of Polihexanide (PHMB), helps reducing bacterial colonisation of the catheter and maintaining good hygienic condition during urinary catheter manipulations. Uro-Tainer® Polihexanide 0.02% is a ready-to-use, disposable system. It consists of a PVC-free bag containing 100 ml of sterile solution, a flexible tube fitted with a clamp, and a sterile universal connector protected by a plastic cap with a tamperproof seal. The system is over-wrapped in a protective plastic envelope.

Dosage
The regime to be used varies from user to user. Up to one or two irrigations per day may be required.

Overdosage
The recommended frequency for use is up to one or two times per day. If the product is used more frequently, no adverse events are expected but no clinical data exists concerning this issue.

Instructions for use
Refer to the illustrated instructions for use on the next page. If the liquid exits from the urethra during the irrigation, the catheter may no longer be in the bladder and the patient may require a new catheter. If the liquid does not flow, the catheter may be kinked in the bladder or it may be blocked and may require changing. Apply by gravity feed, avoid force. Apply using aseptic technique.

Adverse events
Polihexanide can cause allergic reactions such as itching (urticaria) and rashes (exanthema). In rare cases (less than 1 out of 10,000), anaphylactic shock has been reported.

Contraindications
Uro-Tainer® Polihexanide 0.02% should not be used:
- In case of hypersensitivity (allergy) to polihexanide, chlorhexidine, or excipient of the solution.

- In case of cystitis or other uro-genital condition that can produce haematuria (blood in the urine).
- Uro-Tainer® Polihexanide 0.02% should not be used for several days after surgery on the bladder or the urinary tract.
- Avoid contact with open wounds, the inner and middle ear, the central nervous system, eyes, hyaline cartilage and meninges.

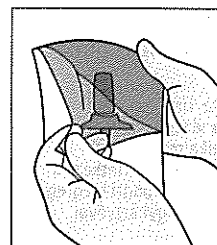
- Important information**
- The product is intended as a rinsing solution and must never be administered intravenously.
 - The product has to be used by professional users or by instructed patients only.
 - Precautions should be taken when operating on patients with spinal injuries because of the risk of autonomic dysreflexia.
 - Device should not be used on a long-term basis in people with tendency of hyponatraemia.
 - The solution is not a vehicle for additives. It must not be used for the dissolution of medication.
 - Only to be used if the overwrapping, the contents and the sealing cap are intact, and the solution is clear.
 - This is a single-use system. After opening, it must be used and disposed of promptly and in an appropriate way. Dispose any partially used sachets and any unused solution. Re-use of single-use devices creates a potential risk for patient or user.
 - Store out of the reach of children.
 - Do not swallow.
 - There is no evidence of any mutagenic or embryo-toxic effects of the ingredients. Since there is no systemic re-sorption of Polihexanide, a pass over of the ingredients to the breast milk is unlikely.
 - Due to the lack of relevant trials and long-term clinical experience with pregnant women, breastfeeding women, newborns and infants this product should only be used after careful medical consultation.
 - This medical device is tested for endotoxins in accordance with the Ph. Eur.
 - Do not use for injections.

Expiry date
Use before the date marked expiry date (M) on the back of the sachet.

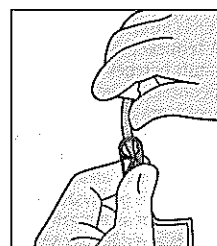
Latest Information update
09/2016

The Uro-Tainer® Polihexanide 0.02% sachet is supplied sterile and should not be removed from its overwrapping until required for use. If desired, bring solution to body temperature by immersing the wrapped sachet in warm water.

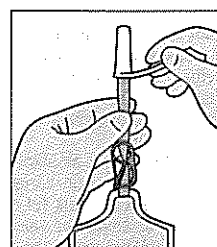
1. Tear open overwrapping and remove Uro-Tainer® sachet.



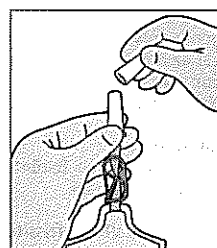
2. Close Uro-Tainer® tube with plastic clamp.



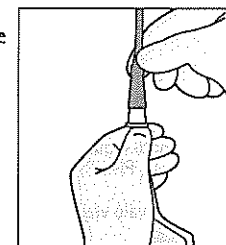
3. Remove tamper proof seal.



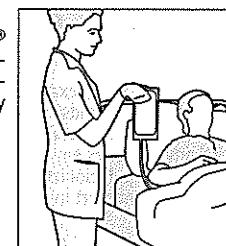
4. Twist and withdraw cap without touching sterile connector.



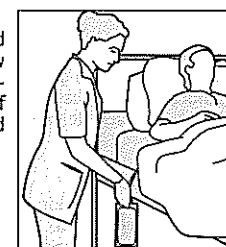
5. Insert connector into the catheter funnel.



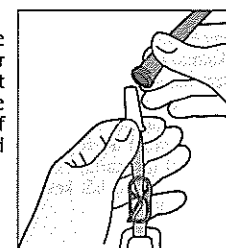
6. Holding the Uro-Tainer® above the level of the bladder, release the clamp to allow the fluid to drain in by gravity.



7. When the fluid has stopped draining in (this takes a few minutes), lower the Uro-Tainer® below the level of the bladder to drain fluid back into the bag.



8. Clamp tube and remove the connector from the catheter by turning gently. Connect the catheter to a sterile drainage bag. Dispose of Uro-Tainer® sachet and wash hands.



Do not re-use, for single use only. Discard properly after use.