TauroLock™ U25000

Catalogue # TP-05

A. Description and Specifications

TauroLock™-U25.000 is a catheter lock solution indicated for patients who use a port or a silicone or polyurethane catheter-based device as venous vascular access. TauroLock™-U25.000 is to be instilled in the device lumens between treatments in order to make the internal flow passages resistant to clot formation and hostile to bacterial and fungal growth. The solution is withdrawn prior to the next treatment. TauroLock™- U25.000 is to be used by healthcare professionals and users trained by health care professionals. TauroLock™-U25.000 contains substances to ensure patency and provide infection control in the device. Active ingredients in TauroLock™-U25.000 are taurolidine, citrate (4 %) and urokinase (25.000 IU; human origin). Other components include water for injection and PVP. The pH is adjusted with citrate and/or sodium hydroxide. One unit of TauroLock™-U25.000 contains one vial with freeze dried powder and one container of TauroLock™ for dissolving it. The solution should be prepared immediately before use. If the solution is stored at 2–8 °C it must be used latest after 5 hours.
Note: For complete details of catheter-based venous vascular access products, consult the manufacturer's instructions or clinician's manual.

B. Intended purpose

TauroLock™-U25.000 is a catheter lock solution to be used with devices for venous access (catheter-based vascular access devices or ports). It is to be instilled into the device at the termination of a treatment to ensure patency and provide infection control in the device.

C. Contraindications

TauroLock™-U25.000 is contraindicated for patients with a known allergy to taurolidine, citrate or urokinase or when a patient is currently taking medication with known adverse interaction to citrate, taurolidine or urokinase. TauroLock™-U25.000 is also contraindicated for patients with increased bleeding risk.

D. Cautions

1. Do not use if primary packaging (glass, septum) is damaged.
2. Do not use if the solution (before and after reconstitution) contains precipitate or has any type of suspended particulate matters.
3. As a consumable TauroLock™-U25.000 is for single use only. The reconstituted solution may be applied to different patients. Once instilled into the catheter the solution must not be used again after aspiration. Reuse creates a potential contamination risk for the patient.
4. TauroLock™-U25.000 is not for systemic injection. TauroLock™-U25.000 must be used as a catheter lock solution as described in the access device's instructions for use. Failure to adhere to these instructions may result in inadvertent systemic injection of the solution.
5. The reconstituted solution has been demonstrated to be stable for 5 hours at 2–8 °C. From a microbiological point of view, the product should be used immediately after reconstitution but not later than 5 hours after reconstitution. Multiple punctures of the container increase the risk of contamination.
6. In the event that access device patency is compromised follow institutional protocol for restoring flow.
7. The specific fill volume of the access device has to be strictly respected.
8. If aspiration is not possible or if healthcare professional decides that aspiration of TauroLock™-U25.000 is not appropriate (blood in the catheter, e. g. in parenteral nutrition), slow flushing (not more than 1 mL per 3 seconds) of the catheter lock solution may be considered. Taurolidine and citrate do not induce any systemic effect. The potential systemic effect of urokinase needs to be considered if flushed. Regular flushing with TauroLock™-U25.000 may increase the risk of allergic reaction. If the access device has previously been blocked with non-antimicrobial lock solutions (e.g., with heparin, low concentrated citrate or saline) there is an increased probability of a presence of biofilm with viable organisms and endotoxins. This should be considered if it is decided to flush a catheter lock solution like TauroLock™-U25.000.
9. The concentration of the antimicrobial compound is near to saturation. If not stored or transported according to the instructions under section H, precipitation can occur in the product. Do not use such a precipitated product.
10. Blood drawn from catheters locked with TauroLock™-U25.000 shall not be used for measurement of blood parameters (due to potential falsification).

E. Adverse Effects

Assessment of adverse effects is based on the following definitions of incidence:

Very common	Common	Uncommon	Rare	Very rare	Not known
≥ 1/10	≥ 1/100 - < 1/10	≥ 1/1.000 - < 1/100	≥ 1/100.000 - < 1/1.000	< 1/100.000	cannot be estimated from the available data

The following undesired effects may occur: Anaphylaxis (very rare); Bleeding (very rare); mild Hypocalcemia (common). There are no known risks associated with concomitant systemic antibiotic therapy or exposure to magnetic fields.

F. Instillation of TauroLock™-U25.000

Follow the manufacturer's instructions that accompany the particular venous vascular access product utilized. Specific catheter lock volumes are associated with each device.

1. Flush the device with 10 mL of saline.
2. Prepare TauroLock™-U25.000 ready to use solution:
   Single dose (packaging configuration 5 x 5 mL): Dissolve Urokinase by adding 5 mL of TauroLock™ ampoule to the vial (use a non-coring needle!) to obtain 5 mL of TauroLock™-U25.000.
   Multi-dose (packaging configuration 10 x 10 mL): Dissolve Urokinase by adding about 5 mL of TauroLock™ to the urokinase vial (use a non-coring needle!). Withdraw the clear solution of Urokinase/TauroLock™ with an appropriate syringe and add the solution to the remaining quantity of TauroLock™. Homogenize the solution by gently shaking the vial to obtain 10 mL of TauroLock™-U25.000.
   For all packaging variants: Withdraw the required volume of the clear solution of TauroLock™-U25.000 from the vial using an appropriate syringe. The reconstituted solution should be used immediately. If the solution is stored at 2–8 °C it must be used latest after 5 hours. To prevent contaminations, aseptic handling procedures (e.g. non-touching technique, closed vials, etc) must be followed during handling and storage of the reconstituted solution.
3. Instill TauroLock™-U25.000 slowly (not more than 1 mL per second) into the access device in a quantity sufficient to fill the lumen completely. **Consult the manufacturer's instructions for the specific fill volume or specify fill volume during implantation. The volume has to be strictly respected.** TauroLock™-U25.000 will remain inside the access device until the next treatment (for a maximum of 30 days).
4. Prior to the next treatment, TauroLock™-U25.000 must be aspirated and discarded according to the institution's policy for infectious waste disposal.
5. Flush the device with 10 mL of saline.

G. Special patient groups

No data are available for pregnant and breastfeeding women, as well as children. For safety reasons TauroLock™-U25.000 should not be used during pregnancy and breastfeeding and in children.

H. Storage and shipment

TauroLock™-U25.000 must be stored at a temperature of 15 to 25°C and must not be shipped at freezing temperature. Do not freeze.

I. Packaging configuration

The following packaging configuration is available for TauroLock™-U25.000:
Single dose: 5 x 5 mL TauroLock™-U25.000 (5 mL TauroLock™-U25.000 consists of 1 glass vial of freeze-dried powder and one glass ampoule of TauroLock™ as solvent).
Multi dose: 10 x 10 mL TauroLock™-U25.000 (10 mL TauroLock™-U25.000 consists of 1 glass vial of freeze-dried powder with 50.000 IU Urokinase and one glass vial with 10 mL of TauroLock™ as solvent).

J. Further Information

Please refer to the following address for additional information regarding safety and clinical performance:
https://ec.europa.eu/tools/eudamed (Basic UDI-DI 426018822-05-T4)

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MD Medical Device.
Contains a medicinal substance.
Do not use when package is damaged.
Read instruction for use.
Single use.
Non-pyrogenic.
STERILE A Sterile, aseptic fill, single sterile barrier system.
CE 0123 CE acc. Regulation (EU) 2017/745 (EU MDR), notified body: TÜV SÜD PRODUCT SERVICE GmbH.