TauroLock™ U25000

Catalogue # TP-05

A. Description and Specifications

TauroLock™-U25.000 contains substances to ensure patency and provide infection control in the device. It is used with devices for venous access e.g. a port or a catheter-based vascular access device. TauroLock™-U25.000 is instilled in the device lumen 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 The solution is withdrawn prior to the next treatment. Active ingredients in TauroLock™-U25.000 are (cyclo)-taurolidine, citrate (4%) and urokinase (25.000 IU). 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 5 mL ampoule of TauroLock™ for dissolving it. The solution must be prepared immediately before use.

Note: For complete details of catheter-based venous vascular access products, consult the manufacturer's instructions or clinician's manual.

B. Indications

TauroLock™-U25.000 is indicated for those patients who use a port or a silicone or polyurethane catheter-based device as venous vascular access. TauroLock™-U25.000 is intended to be used as a catheter lock solution by healthcare professionals. It is to be instilled into the device at the termination of a treatment to ensure patency and provide infection control in the device. TauroLock™-U25.000 is withdrawn prior to subsequent treatments (see F4).

C. Contraindications

TauroLock™-U25.000 is contraindicated for patients with a known allergy to (cyclo)-taurolidine, citrate or urokinase or when a patient is currently taking medication with known adverse interaction to citrate, (cyclo)-taurolidine or urokinase.

D. Cautions

1. As a consumable TauroLock™-U25.000 is for single use only. Reuse creates a potential contamination risk for the patient.
2. 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.
3. In the event that access device patency is compromised follow institutional protocol for restoring flow.
4. The specific fill volume of the access device has to be strictly respected with infants and children less than two years of age due to citrate as an active ingredient.
5. In access devices which were blocked regularly with non-antimicrobial lock solutions (e.g. with heparin, low concentrated citrate or saline) prior to application of TauroLock™-U25.000, viable organisms and endotoxins may be released from the biofilm. The lock solution must be aspirated before the next treatment to prevent very rare anaphylactic reactions which are not attributable to the active ingredients.
6. 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.
7. 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:

- Very rare: Anaphylaxis, Bleeding
- Common: Hypocalcaemia

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. Dissolve Urokinase by adding 5 mL of TauroLock™ to the vial (use a non-coring needle!) and withdraw the clear solution of TauroLock™-U25.000 from the vial using an appropriate syringe. The reconstituted solution has to be used immediately.
3. Instill TauroLock™-U25.000 slowly (not more than 1 mL per second, infants and children less than two years of age not more than 1 mL per 5 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. Pregnancy and Breastfeeding

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

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: 5 x 5 mL TauroLock™-U25.000 (5 mL TauroLock™-U25.000 consists of 1 vial of freeze dried powder and one ampoule of TauroLock™ as solvent).

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STERILE A Sterile, aseptic fill.

Read instruction for use.

Single use.

Do not use when package is damaged.

CE 0123 CE acc. MDD 93/42/EEC, notified body: TÜV SÜD PRODUCT SERVICE GmbH.