TauroLock™ HEP 500

Catalogue # TP-02

A. Description and Specifications

TauroLock™-HEP500 contains anticoagulants and antimicrobial substances. It is to be used with a catheter-based vascular access device for hemodialysis. It 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 The solution must be withdrawn prior to initiating the next treatment. Active ingredients in TauroLock™-HEP500 are (cyclo)-taurolidine, citrate (4%) and heparin (mucosa, 500 IU/mL). Other components include water for injection. The pH is adjusted with citrate and/or sodium hydroxide. The product is sterile filter processed and supplied as a clear, sterile, non-pyrogenic solution.

Note:

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

B. Indications

TauroLock™-HEP500 is indicated for those hemodialysis patients who use a silicone or polyurethane catheter-based device as vascular access. TauroLock™-HEP500 is intended to be used as a catheter lock solution. It is to be instilled into the device at the termination of a treatment and withdrawn prior to initiating subsequent treatments (see F4).

C. Contraindications

TauroLock™-HEP500 is contraindicated for patients with a known allergy to (cyclo)-taurolidine, citrate or heparin (mucosa) or when a patient is currently taking medication with known adverse interaction to citrate, heparin or (cyclo)-taurolidine. TauroLock™-HEP500 is also contraindicated for patients with heparin-induced thrombocytopenia or increased bleeding risk.

D. Cautions

1. As a consumable TauroLock™-HEP500 is for single use only. Reuse creates a potential contamination risk for the patient.
2. TauroLock™-HEP500 is not for systemic injection. TauroLock™-HEP500 must be used as a catheter lock solution as described in the access device's instruction for use. Failure to adhere to these instructions may result in inadvertent systemic injection of the solution. Once instilled into the catheter the solution must not be used again after aspiration.
3. The vial* is a multi dose container. Once punctured it must be used within 48 hours. The ampoule is for single dose only due to potential risk of contamination.
4. Some patient populations using TauroLock™-HEP500 antimicrobial lock solution may experience a higher frequency of blood clots in the catheter lumen. In the event that access device patency is compromised, follow institutional protocol for restoring flow.
5. 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.
6. 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™-HEP500, 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.
7. 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.

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); mild Hypocalcemia (common). There are no known risks associated with concomitant systemic antibiotic therapy or exposure to magnetic fields.

F. Instillation of TauroLock™-HEP500

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

1. Flush the device with 10 mL of saline.
2. Withdraw TauroLock™-HEP500 from the container using an appropriate syringe.
3. Instill TauroLock™-HEP500 slowly (not more than 1 mL per second, infants and children less than two years of age not more than 1 mL per 5 seconds) 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™-HEP500 will remain inside the access device until the next treatment (for a maximum of 30 days).
4. Prior to the next treatment, TauroLock™-HEP500 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™-HEP500 should not be used during pregnancy and breastfeeding.

H. Storage and shipment

TauroLock™-HEP500 must be stored at a temperature of 15 to 30°C and must not be shipped at freezing temperature. Do not freeze.

I. Packaging configuration

The following packaging configurations are available for TauroLock™-HEP500: 10 x 5 mL TauroLock™-HEP500 ampoules (single dose container). 100 x 10 mL TauroLock™-HEP500 vials* (multi dose container).

* Vials are not available in Australia.

State: 17.05.2019

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STERILE A Sterile, aseptic fill.

Read instruction for use.

Single use. The ampoule is a single dose and the vial* a multi dose container.

Do not use when package is damaged.

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