TauroLock™

Catalogue # TP-01

A. Description and Specifications

TauroLock™ 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™ 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 The solution must be withdrawn prior to initiating the next treatment. TauroLock™ is to be used by healthcare professionals and users trained by health care professionals. TauroLock™ contains substances to ensure patency and provide infection control in the device. Active ingredients in TauroLock™ are taurolidine and citrate (4%). Other components include water for injection and PVP. 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 venous vascular access products, consult the manufacturer's instructions or clinician's manual.

B. Intended Purpose

TauroLock™ 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™ is contraindicated for patients with a known allergy to citrate or taurolidine, or when a patient is currently taking medication with known adverse interaction to citrate or taurolidine.

D. Cautions

1. As a consumable TauroLock™ is for single use only. Once instilled into the catheter the solution must not be used again after aspiration. Reuse creates a potential contamination risk for the patient.
2. TauroLock™ is not for systemic injection. TauroLock™ 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.
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. In the event that access device patency is compromised, follow institutional protocol for restoring flow. Note: In case of patency problems other TauroLock™ variants such as TauroLock™-HEP100, TauroLock™-HEP500 or TauroLock™-U25.000, which contain additional anticoagulant or fibrinolytic agents, are available.
5. The specific filling volume of the access device has to be strictly respected with infants and children less than two years (of age) old due to citrate as an active ingredient.
6. If aspiration is not possible or if healthcare professional decides that aspiration of TauroLock™ 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. In infants and children less than two years of age flushing should only be performed if aspiration is not possible. Due to the content of citrate flushing should be performed very slowly (not more than 1 mL per 8 seconds). 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™.
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.
8. Blood drawn from catheters locked with TauroLock™ 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); mild Hypocalcemia (common). There are no known risks associated with concomitant systemic antibiotic therapy or exposure to magnetic fields.

F. Instillation of TauroLock™

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. Withdraw TauroLock™ from the container using an appropriate syringe.
3. Instill TauroLock™ 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™ will remain inside the access device until the next treatment (up to a maximum of 30 days).
4. Prior to the next treatment, TauroLock must be aspirated and discarded in accordance with 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™ should not be used during pregnancy and breastfeeding.

H. Storage and shipment

TauroLock™ 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™: 10 x 3 mL TauroLock™ ampoules (single dose container). 10 x 5 mL TauroLock™ ampoules (single dose container). 100 x 10 mL TauroLock™ vials* (multi dose container).

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: 426018822-01-SQ)

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* Vials not available in Australia

TauroPharm GmbH · August-Bebel-Straße 51 · D-97297 Waldbüttelbrunn · Germany
Tel: +49 931 304 299 0 · Fax: +49 931 304 299 29

MD Medical Device.

Contains a medicinal substance.

Do not use when package is damaged.

Non-pyrogenic.

Read instruction for use.

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

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.