NutriLock™

Catalogue # TP-07

A. Description and Specification

NutriLock™ contains an antimicrobial substance. It is to be used with a port or a catheter-based vascular access device for parenteral nutrition and medication. It is to be instilled in the device lumens between treatments in order to maintain device patency and to make the internal flow passages hostile to bacterial and fungal growth. The solution must be withdrawn prior to initiating the next treatment. Active ingredient in NutriLock™ is taurolidine. Other components include water for injection and PVP. The pH is adjusted with sodium hydroxide. The product is supplied as a clear, sterile and non-pyrogenic solution.

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

B. Indications

NutriLock™ is indicated for those patients who use a port or a silicone or polyurethane catheter-based device as vascular access for parenteral nutrition or medication. NutriLock™ 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 It is to be instilled into the device at the termination of a treatment and should be withdrawn prior to initiating subsequent treatments (see F4).

C. Contraindications

NutriLock™ is contraindicated for patients with a known allergy to taurolidine or any of the other ingredients, or when a patient is currently taking medication with known adverse interaction to taurolidine.

D. Cautions

1. As a consumable NutriLock™ is for single use only. Aspirated solution must be discarded.
2. NutriLock™ is not for systemic injection. NutriLock™ 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. Data for NutriLock™ use in dialysis catheters are insufficient. Therefore we do not recommend the use of NutriLock™ in dialysis catheters.
4. Some patient populations using NutriLock™ antimicrobial lock solution may experience a higher frequency of occlusion problems. In the event that access device patency is compromised, follow institutional protocol for restoring flow. In addition, heparin may be used as an accessory to NutriLock™ in these patient populations to decrease the incidence of blood clots. If heparin is used as an additive do not add more than 0.6 mL volume of heparin to 3 mL volume of NutriLock™. The maximum concentration of heparin used is 25,000 IU/mL. If heparin is added the combined solution should not be flushed into the bloodstream due to the systemic effect of heparin. Alternatively ready-to-use solutions (TauroLock™-Hep100, TauroLock™-Hep500, TauroLock™-U25.000) may be used.
5. In access devices which have previously been locked with non-antimicrobial lock solutions (e.g. with heparin, low concentrated citrate or saline) prior to the use of NutriLock™, viable organisms and endotoxins may be released from the biofilm. In this situation the lock solution must be aspirated prior to 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 product with visible particles.

E. Adverse Effects

To date, there are no known adverse effects in humans due to the active ingredient concentrations in NutriLock™ when used as directed. There are no known risks associated with concomitant systemic antibiotic therapy or exposure to magnetic fields.

F. Application of NutriLock™

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 NutriLock™ from the container using an appropriate syringe.
3. Instill NutriLock™ 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. NutriLock™ will remain inside the access device until the next treatment (up to a maximum of 30 days).
4. Prior to the next treatment, NutriLock™ must be aspirated and discarded in accordance with the institution's waste policy. If aspiration of NutriLock™ is not possible, slow flushing of NutriLock™ (not more than 1 mL per 3 seconds) prior to the next treatment does not cause any systemic effect due to its active ingredient.
5. Flush the device with 10 mL of saline.

G. Pregnancy and Breastfeeding/Children

No data are available for pregnant and breastfeeding women. For safety reasons NutriLock™ should not be used during pregnancy and breastfeeding. The safety and efficiency of NutriLock™ have not been investigated in children before skeletal maturity.

H. Storage and shipment

Store at controlled room temperature 15-25 °C. Do not store in a refrigerator.

I. Packaging configuration

The following packaging configuration is available for NutriLock™: 10 x 3 mL NutriLock™ ampoules (single dose container)

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

STERILE Sterilized using steam or dry heat.

Read instruction for use.

Do not re-use.

Do not use when package is damaged.

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