The Neutrolin® product is used for the prevention of Catheter Related Bloodstream Infections (CRBI) and the maintenance of catheter flow for patients receiving haemodialysis treatment using tunneled, cuffed central venous haemodialysis catheters. Neutrolin® may also be used in smokers cuffed cen- tral venous catheters between total parenteral nutrition (TPN) infusions, in chemotherapy catheters between chemotherapy infusions and infusions, and in single use units (SU) catheters between intravenous treatments. Neutrolin® is supplied as 20 mL vials filled with 4.5 mL, 5.0 mL, or 5.8 mL of solution for instillation in central venous catheters (CVC) between haemodialysis, chemotherapy, parenteral feeding, or other IV treatments. The intent for the solution is to be instilled in catheters using a volume matching the volume of the CVC catheter, which typically varies from 3.0 mL to 5.0 mL. Neutrolin® will be removed prior to subsequent use of the catheter. The product is not intended be given intravenously or systematically during normal use.

Neutrolin® solution is comprised of the following active ingre- dients: taurolidine 3.2%, citrate 3.5%, and heparin. Other ingre- dients include Water for Injection (WFI). The pH is adjusted with citric acid and sodium hydroxide. The product is sterile and preserved with a sterile, nonpyrogenic solution. Each single-use vial contains 4.0 mL, 5.0 mL, or 5.8 mL of solution that must not be re-opened or broken.

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

Indications for use
Neutrolin® is indicated for the prevention of catheter related bloodstream infection (CRBI) and maintenance of catheter pat- iency in haemodialysis (HD) patients using a tunneled, cuffed silicone catheters or polyurethane Central venous CVC for va- scular access. Neutrolin® is intended to be used as a Catheter Lock Solution (CLS), and will be instilled into the CVC at the termination of each haemodialysis treatment and withdrawn prior to the subsequent haemodialysis treatment. Neutrolin® is also indicated for the prevention of CRBI in the following three patient populations: 1) cancer patients actively receiving chemotherapy, cy or hydrazine, or IV medications via a central venous catheter (CVC); 2) patients receiving total parenteral nutrition (TPN) via a CVC; and 3) patients receiving infusion and/or fluids via CVCs in intensive or critical care units (ICU, CCU, PACU, OR, and Urgent Care Centers).

Contraindications
Neutrolin® is contraindicated for patients with a known allergy to taurolidine, citrate, or heparin, or patients sensitive to other medication with known adverse interaction to taurolidine, citrate, or heparin. Neutrolin® should not be given to subjects with known heparin-induced thrombocytopenia. Neutrolin® is available for pregnant and lacta- ting women. For safety reasons Neutrolin® should not be used during pregnancy and breastfeeding. Consult with a medical professional in the event Neutrolin® is required and prior to its use.

Warnings:
1. The Neutrolin® vial are intended for single use only.
2. The Neutrolin® in the sterile vial is not intended for systemic injection. Neutrolin® must be used as a Catheter Lock Solution (CLS) as described in the access device’s instructions for use. Failure to adhere to these instructions may result in inept venous infection of the solution.
3. Neutrolin® cannot be re-sterilized by autoclaving or any other terminal sterilization method as this will denature the product.
4. The Neutrolin® vials and sealed caps must remain intact and show no sign of damage prior to use. Neutrolin® pro- duction showing evidence of damage may be sterile and cannot be re-sterilized by any terminal sterilization me- thod. If the vial, cap, or rubber stopper show any sign of damage, the product must not be used and should be discarded according to the institution’s biohazardous waste policy.
5. Discard and use the vials in cloudy or if there is presence of precipitate.

Adverse Effects
Podalic: There are no known serious adverse effects in hu- mans due to the active ingredient at concentrations con- tained in Neutrolin® device. For adverse effects there are no known associated risks with this non-systemic antibiotic therapy or exposure to magnetic fields.

Neutrolin® may cause tingling or pruriitus in the subcuta- neous or intramuscular space, or in a peripheral vein.

As Neutrolin® contains heparin, it could be associated with the development of heparin induced thrombocytopenia. The most frequent transient adverse effects reported for similar products include a brief arterial or venous sensation (dyspha- sia) or shin laboratories sensation (paresthesia).

Instillation Instructions for Neutrolin® CLS:
Neutrolin® should only be used under the supervision of a medical professional.

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

The following procedures will be followed when using the Neutrolin® Catheter Lock Solution (CLS) via a single device with 30 mL of saline. 1. Withdraw Neutrolin® CLS from the vial using a 3,4, or smaller syringe (to ensure accurate volume). 2. Open the syringe. 3. Invert Neutrolin® into the device in a quantity sufficient to fill the catheter lumen. Consult the manu- facturer’s instructions for specific fill volume. Neutrolin® is intended to remain inside the access device until its next use. 4. Prior to initiation of intravenous treatment, Neutrolin® should be withdrawn from the catheter and discarded according to the institution’s biohazardous waste policy. 5. Prior to initiation of TPN infusion, chemotherapy, intrave- nous fluids, or medications, the same procedure as in #4 should be used.

Storage
The Neutrolin® vials must be stored at a controlled room temperature (15°C ±5°C). Do not freeze. These products are intended only for single use and any unused portion of the solution withdrawn from the vial must be discarded according to the institution’s biohazardous waste policy. Any unused portion remaining in the vials must be discarded according to the institution’s biohazardous waste policy.