

Neutrolin®

Catheter Lock Solution for instillation into central venous catheters between haemodialysis, chemotherapy, parenteral feedings, and other intravenous treatments

Read all of this leaflet carefully before you start using this product because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

The Neutrolin® product is used for the prevention of Catheter Related Bloodstream Infections (CRBI) and the maintenance of catheter blood flow for patients receiving haemodialysis treatment using tunneled, cuffed central venous haemodialysis catheters. Neutrolin® may also be used in chronic cuffed central venous catheters between total parenteral nutrition (TPN) infusions, in chemotherapy catheters between chemotherapy infusions and hydration, and intensive care unit (ICU) catheters between intravenous treatments.

Neutrolin® is supplied in 10 mL vials filled with 4.0 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 fill volume of the CVC catheter, which typically varies from 3.0-5.0 mL. Neutrolin® will be removed prior to subsequent use of the catheter. The product is not intended to be given intravenously or systemically during normal use.

Neutrolin® solution is comprised of the following active ingredients: taurolidine 1.35%, citrate 3.5%, and heparin 1,000 u/mL. Therefore, a patient with a 5 mL catheter will have up to a maximum of 67.5 mg of taurolidine, 175 mg citrate, and 5,000 units of heparin instilled into their catheter.

Dosing instructions for Neutrolin® are as follows:

Description and Specifications

Neutrolin® contains antimicrobial and anticoagulant substances. It is intended to be used as a Catheter Lock Solution in CVC catheters. For TPN, Neutrolin® is to be used as a means to keep the catheter patent between infusions of TPN; it is not to be used as a solution for continuous drip. Neutrolin® is to be instilled in the device lumens between haemodialysis, chemotherapy, TPN, or other IV treatments in order to make the catheter lumen hostile to bacterial and fungal growth and resistant to clot formation. The solution should be withdrawn prior to initiating subsequent treatments. Active ingredients in Neutrolin® are taurolidine, citrate and heparin. Other ingredients include Water for Injection (WFI). The pH is adjusted with citric acid and sodium hydroxide. The product is sterile filtered and supplied as a clear, sterile, nonpyrogenic solution. Each single-use vial contains 4.0 mL, 5.0 mL or 5.8 mL of solution. Do not use if the seal is 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 patency in haemodialysis (HD) patients using a tunneled, cuffed silicone or polyurethane Central Venous Catheter (CVC) for vascular 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, IV hydration, or IV medications via a central venous catheter (CVC); 2) patients receiving total parenteral nutrition (TPN) via a CVC and 3) patients receiving medication and IV fluids via CVCs in intensive or critical care units (ICUs, CCUs, SCUs, NCCUs, and Urgent Care Centers).

Contraindications

Neutrolin® is contraindicated for patients with a known allergy to taurolidine, citrate, or heparin, or when a patient is currently taking another medication with known adverse interaction to taurolidine, citrate, or heparin. Neutrolin® should not be given to subjects with known heparin-induced thrombocytopenia.

No data using Neutrolin® is available for pregnant and lactating 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® vials are intended for single use only.
2. The Neutrolin® in the sterile vials 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 inadvertent systemic injection of the solution.

3. Neutrolin® cannot be re-sterilized by autoclave 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® product showing evidence of damage may not be sterile and cannot be re-sterilized by any terminal sterilization method. 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. Do not use if the solution is cloudy or if there is presence of precipitate.

Adverse Effects

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

Neutrolin® may cause stinging if injected into the subcutaneous or intramuscular space, or into a peripheral vein.

As Neutrolin® contains heparin it could be associated with the development of heparin-induced thrombocytopenia.

The most frequent minor adverse effects reported for similar products include a brief abnormal taste sensation (dysgeusia) and/or a brief tingling 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 particular 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) vials:

1. Flush the device with 10 mL of saline.
2. Withdraw Neutrolin® CLS from the vial using a 3 mL or smaller syringe (to ensure accurate volume). Use one syringe for each lumen.
3. Instill Neutrolin® into the access device in a quantity sufficient to fill the catheter lumen. Consult the manufacturer's instructions for specific fill volume. Neutrolin® is intended to remain inside the access device until its next use to deliver treatment.
4. Prior to initiation of the next 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, intravenous fluids / medications, the same procedure as in #4 should be used.

Storage

The Neutrolin® vials must be stored at a controlled room temperature of 15 to 25°C.

Do not freeze. These products are intended only for single use and any unused portion of the solution withdrawn from the vials 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.



Fragile - Handle with care



Do not use if package is damaged



For SINGLE Use Only



CorMedix Inc.
400 Connell Drive, Suite 5000
Berkeley Heights, NJ 07922
Made in Germany



EMERGO EUROPE
Prinsesgracht 20 2514 AP
The Hague, The Netherlands



This Product is not to be re-sterilized



Date of Issue: 2018-04 v3.0
Part #: CN05