

Dialysis efficiency – effectively protected

Catheter lock solution with taurolidine, heparin and citrate



- ▶ Prevents thrombosis!
- ▶ Protects against infection!



Dialysis efficiency – effectively protected

Catheter lock solution taurolidine, heparin and citrate

Neutrolin®

First-in-class, non-antibiotic solution that prevents infections and thrombosis associated with central venous catheters.

Neutrolin®

- Prevents thrombosis¹
- Protects against infection¹



- **Neutrolin®** consists of taurolidine 1.35%, heparin 1,000 units/mL and citrate 3.5%:
 - Taurolidine 1.35% is a synthetic broad-spectrum anti-bacterial and anti-fungal compound that is metabolized to the amino acid taurine in humans, which limits its toxicity for clinical use
 - Heparin 1,000 units/mL is added to Neutrolin as a well-established anticoagulant
 - Citrate 3.5% is added as a buffer to ensure that taurolidine remains in solution at ~ pH 6
- **Neutrolin®** is an antimicrobial and anticoagulant catheter lock solution for hemodialysis patients
- **Neutrolin®** provides protection against catheter-related blood stream infections (CRBSI) and helps to maintain catheter patency

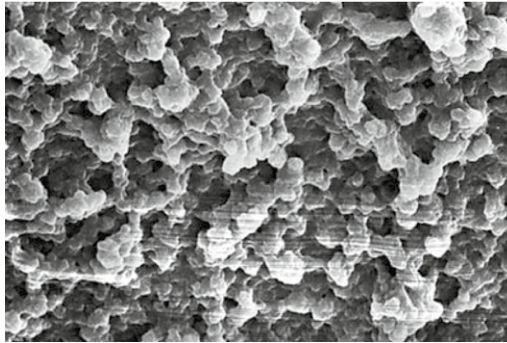
Attributes of Neutrolin® which improve lock effectiveness²:

- Broad-spectrum antimicrobial effect against bacteria and fungi
- Safe and compatible with tissue and blood
- No evidence of bacterial resistance in human
- No systemic pharmacological effect
- Inactivation of endotoxin
- Reduces adherence of bacteria and blood to surfaces

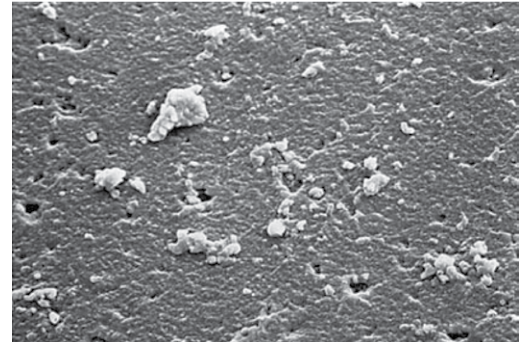
Active ingredient – taurolidine

- Taurolidine is a unique nontoxic substance that eliminates binding of bacteria and some fungi to the surface
- Taurolidine is NOT an antibiotic and it has never demonstrated bacterial resistance
- Taurolidine is a broad-spectrum antimicrobial active substance against virulent bacteria and fungi, responsible for most HD infections
- Taurolidine has proven effective in preventing catheter colonization at the planktonic level and eradication of a developed biofilm in several types of in vitro tests

Neutrolin® and biofilm formation



Heparin 7 months



Neutrolin® 5 months

Figure 1 shows two scanning electron microscope (SEM) photos of the luminal surfaces from two different catheters. The left catheter was removed from the HD patient who had been using a conventional heparin lock for 7 months. The photo on the right of an HD patient using Neutrolin® locked catheter has no evidence of any biofilm after 5 months in vivo.⁴

Validated Clinical Utility in “EU Real World” Setting – Neutrolin® Usage Monitoring Program (NUMP)

- From January 2014 to November 2015, 19 hemodialysis centers in Germany participated in Neutrolin® Usage Monitoring Program
- 199 HD patients representing 15,122 dialysis sessions over a 22 months period for a total of 35,285 hemodialysis catheter days
- 5 infections and 3 thrombosis events over the 35,285 hemodialysis catheter days
- The primary outcome of our study is to monitor safety and efficacy of Neutrolin® in preventing infection and thrombosis in HD patients

Complication (per 1,000 catheter days)	Historical Benchmark	Neutrolin®	% Reduction in Infection Rate
Infection	3.5 ³	0.142	96.0%
Thrombosis	2–3 ^{4,5}	0.085	96.6%

Figure 2 shows the results of Neutrolin® Usage Monitoring Program

- **Positive results are consistent with prior clinical studies**

*Neutrolin for this study was provided by Biolink Corporation. Composition of Neutrolin was taurolidine 1.35% and citrate 2.61% as citric acid.

1) CDC Guidelines for the Prevention of Intravascular Catheter Related Infections; 2) O'Grady et al., 2011; Morris P, Knechtle SJ. Kidney Transplantation – Principles and Practice. Saunders, 2013. 3) Napalkov P, Felici DM, Chu LK, Jacobs JR, Begelman SM. Incidence of catheter-related complications in patients with central venous or hemodialysis catheters: a health care claims database analysis. BMC Cardiovasc Disord. 2013 Oct 16;13:86. doi: 10.1186/1471-2261-13-86. PubMed PMID: 24131509; PubMed Central PMCID: PMC4015481 4) Quarello F, Forneris G. Prevention of hemodialysis catheter-related bloodstream infection using an antimicrobial lock. Blood Purif. 2002;20(1): 87-92. Review. PubMed PMID: 11803164. 5) Napalkov P, Felici DM, Chu LK, Jacobs JR, Begelman SM. Incidence of catheter-related complications in patients with central venous or hemodialysis catheters: a health care claims database analysis. BMC Cardiovasc Disord. 2013 Oct 16;13:86. doi: 10.1186/1471-2261-13-86. PubMed PMID: 24131509; PubMed Central PMCID: PMC4015481

anti-infective

anti-coagulant

Neutrolin®

- ▶ Prevents thrombosis!
- ▶ Protects against infection!

Neutrolin®
Catheter Lock Solution
Each vial contains 5.0 mL Neutrolin
Use as Directed by Physician
EMERGO EUROPE, Molenbeek 1210
The Hague 14 10

Manufactured by: CorMedix Inc.
145 Rt. 202-206, Bldg. 10
Bridgewater, NJ 08807
2013-08

STERILE A

Available size:
10 x 5.0 ml injection vial

Download instructions
for use as pdf



CorMedix Europe GmbH
An der Richthalle 6
36037 Fulda
Germany

Serviceline: +49 661 380 276-06
Fax: +49 661 380 276-07
Email: info@cormedix-europe.com
Web: www.cormedix-europe.com

CorMedix™
Europe GmbH