DEFENCATH®
Taurolidine and Heparin Catheter Lock Solution

Limited Population

Protect the central line

DefenCath—the first and only FDA-approved catheter lock solution (CLS) proven to significantly reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). This drug is indicated for use in a limited and specific population of patients.[1,2]

INDICATIONS AND USAGE

LIMITED POPULATION: DefenCath® is indicated to reduce the incidence of catheter-related bloodstream infections (CRBSI) in adult patients with kidney failure receiving chronic hemodialysis (HD) through a central venous catheter (CVC). This drug is indicated for use in a limited and specific population of patients.

Limitations of Use

The safety and effectiveness of DefenCath have not been established for use in populations other than adult patients with kidney failure receiving chronic HD through a CVC.

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DefenCath is contraindicated in patients with:

- Known heparin-induced thrombocytopenia (HIT).
- Known hypersensitivity to taurolidine, heparin or the citrate excipient (components of DefenCath), or pork products.

For adult patients with kidney failure receiving chronic HD-CVC, DefenCath delivers[1]:

Broad spectrum activity throughout the lumen against clinically relevant pathogens (including gram-positive and gram-negative bacteria and fungi).[1,3-5*†] DefenCath's active ingredient taurolidine has a nonspecific mechanism of action.[1]

Significant reduction in the risk of CRBSIs by 71% vs heparin control (log-rank p=0.0006), with a safety profile comparable to heparin control.[1-3] See back for more study design information.

DefenCath, with refrigeration-free storage, can be used with commonly used HD-CVCs and is administered similarly to standard of care (heparin).[1,6]

*Clinical significance of *in vitro* data is unknown.

†Active against most isolates of the following pathogens: gram-positive bacteria such as *Staphylococcus aureus* (including methicillin-sensitive *Staphylococcus aureus* [MSSA] and methicillin-resistant *Staphylococcus aureus* [MRSA]), *Staphylococcus epidermidis*, and *Enterococcus faecalis*; gram-negative bacteria such as *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*; and fungi such as *Candida albicans* and *Candida glabrata*.

You can **protect the entire length of the lumen** with the first and only FDA-approved catheter lock solution.[1]

For additional details on the efficacy, safety and risks associated with DefenCath from the pivotal Phase 3 LOCK-IT-100 trial, scan the QR code.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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- Known hypersensitivity to taurolidine, heparin or the citrate excipient (components of DEFENCATH), or pork products.

Please see additional Important Safety Information throughout and the full Prescribing Information.

LOCK-IT-100 was the largest study of catheter lock solutions ever conducted in the US to date[1,2]

Results

	DefenCath (N=397)	Heparin control (N=398)
CAC-adjudicated CRBSI	9 (2.3%)	32 (8%)
Event rate per 1000 catheter-days (95% CI)	0.13 (0.07, 0.26)	0.46 (0.33, 0.66)
Risk reduction (95% CI)*	71% (38%, 86%)†	

*Based on 1 — Hazard Ratio.
†log-rank p=0.0006

For additional details on the efficacy, safety and risks associated with DefenCath from the pivotal Phase 3 LOCK-IT-100 trial, scan the QR code.

Study design:

The efficacy and safety of DefenCath for reducing the incidence of catheter-related bloodstream infections (CRBSIs) in adult patients with kidney failure receiving chronic hemodialysis (HD) was evaluated in LOCK-IT-100, a randomized, double-blind, active-controlled, multicenter trial.[1]

A total of 806 patients were randomized in a 1:1 ratio to receive either DefenCath (taurolidine [13.5 mg/mL], and heparin [1,000 USP Units/mL] [n=397]) or heparin (heparin sodium USP 1,000 units/mL, benzyl alcohol 9.45 mg/mL and sodium chloride 9.0 mg/mL [n=398]) as a catheter lock solution (CLS) and enrollment was not limited to patients with specific types of HD catheters. DefenCath or heparin was instilled into central venous HD catheters at the end of all dialysis sessions and was withdrawn prior to the initiation of the next dialysis session.[1]

Patient population[1]:

- The median age of patients was 63 years (range, 21-94 years)
- 58% identified as male
- 63% identified as White
- The majority of patients (98%) had HD treatment 3 times per week, and 48% had their catheter implanted within 3 months prior to randomization

CRBSI definition[1]:

- A clinical adjudication committee (CAC) assessed the cases of CRBSIs
- The CAC definition for CRBSI included 1 positive blood culture (other than for coagulase-negative staphylococci, which required a confirmatory culture) from a peripheral site or either the arterial or venous catheter hub or the arterial or venous dialysis blood line, and the patient had to have signs and symptoms of infection and no other apparent source of bloodstream infection

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS

- **Heparin-Induced Thrombocytopenia (HIT):** HIT was reported in patients using heparin, a component of DEFENCATH, as a catheter lock solution. If HIT occurs, discontinue DEFENCATH and institute appropriate supportive measures.
- **Drug Hypersensitivity:** Drug hypersensitivity reactions have been reported in patients using heparin, a component of DEFENCATH, as a catheter lock solution. If a hypersensitivity reaction occurs, discontinue DEFENCATH and institute appropriate supportive measures.

ADVERSE REACTIONS

The most frequently reported adverse reactions occurring in ≥2% of patients using DefenCath as a CLS were hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, and thrombocytopenia.

To report SUSPECTED ADVERSE REACTIONS, contact CorMedix Therapeutics at 1-844-424-6345 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Please see the full Prescribing Information.

References: 1. DefenCath (taurolidine and heparin) [prescribing information]. Berkeley Heights, NJ: CorMedix Inc; 2024. **2.** Agarwal AK, Roy-Chaudhury P, Mounts P, Hurlburt E, Pfaffle A, Poggio EC. Taurolidine/heparin lock solution and catheter-related bloodstream infection in hemodialysis: a randomized, double-blind, active-control, phase 3 study. *Clin J Am Soc Nephrol.* 2023;18(11)1446-1455. **3.** Data on file, CorMedix Inc. **4.** Gahlot R, Nigam C, Kumar V, Yadav G, Anupurba S. Catheter-related bloodstream infections. *Int J Crit Illn Inj Sci.* 2014;4(2):162-167. **5.** Shah H, Bosch W, Thompson KM, Hellinger WC. Intravascular catheter-related bloodstream infection. *Neurohospitalist.* 2013;3(3):144-151. **6.** Arechabala MC, Catoni MI, Claro JC, et al. Antimicrobial lock solutions for preventing catheter-related infections in haemodialysis. *Cochrane Database Syst Rev.* 2018;(4):CD010597.

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