

Protect the central line from end-to-end^{1,2}

First-in-class CLS that protects the entire length of the lumen^{1,2}

DefenCath is a combination of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, 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.¹

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.¹

Taurolidine acts as a broad-spectrum antimicrobial by^{1,3*}:

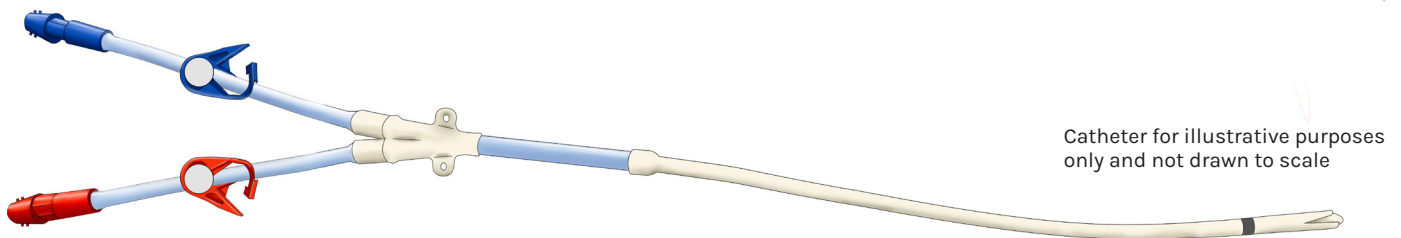
- Employing a non-specific mechanism of action that causes damage to microbial cell walls¹
- Inhibiting adherence of microorganisms to biologic surfaces, which is the first step in biofilm formation, which may occur within 3 days of catheter placement^{1,4,5}

Heparin is an anticoagulant that helps maintain catheter line patency^{1,6}



Broad spectrum antimicrobial activity that **delivers end-to-end protection with no known antimicrobial resistance**^{1,2,4*}

← When instilled into the catheter, DefenCath protects the entire length of the lumen^{1,2} →



*The following *in vitro* data are available, but their clinical significance is unknown. Taurolidine has been shown to be active against most isolates of the following microorganisms^{1,4}:

- Pathogens include gram-positive bacteria: *Staphylococcus aureus* (including methicillin-sensitive *Staphylococcus aureus* [MSSA] and methicillin-resistant *Staphylococcus aureus* [MRSA]), *Staphylococcus epidermidis*, and *Enterococcus faecalis*; gram-negative bacteria: *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*; and fungi: *Candida albicans*, *Candida glabrata*, and *Candida auris* (*Candida auris* *in vitro* data were not submitted and reviewed by the FDA).
- No known antimicrobial resistance.

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

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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.

Please see additional Important Safety Information throughout and the full [Prescribing Information](#).

Administered similarly to current standard-of-care CLS practices^{1,7}

Important reminders while administering DefenCath

- DefenCath is **for instillation in CVCs only**¹
- DefenCath is **not intended for systemic administration**¹
- Do **not** use DefenCath as a catheter lock flush product¹
- Use a 5 mL single dose vial to instill DefenCath into each catheter lumen at the conclusion of each HD session¹
- DefenCath **should be aspirated** from the catheter and discarded prior to the initiation of the next HD session¹
- If DefenCath cannot be aspirated, continue with standard of care CVC preparation and flush with normal saline¹
- If a catheter malfunction is suspected, appropriate standard of care measures should be instituted¹
- Each DefenCath single-dose vial is designed for use with a single patient as a single instillation in the CVC. Discard any unused portion of DefenCath remaining in the vial¹

Protect the central line



Scan or click the QR code or visit **DefenCath.com**



Not Actual Size

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 $\geq 2\%$ of patients using DEFENCATH as a CLS or hemodialysis were hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, and thrombocytopenia.

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

Please see the full [Prescribing Information](#).

References: 1. DefenCath[®] (taurolidine and heparin) catheter lock solution Prescribing Information, CorMedix, Berkeley Heights, New Jersey. 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 Nov 1;18(11):1446-1455. doi:10.2215/CJN.0000000000000278 3. Data on file, CorMedix Inc. 4. Reidenberg BE, Jenkins SG, Crandon JL, et al. In vitro activity of taurolidine against clinical *Candida auris* isolates: relevance to catheter-related bloodstream infections. *Antimicrob Agents Chemother*. 2024;68(7):e0038124 5. Yousif A, Jamal MA, Raad I. Biofilm-based central line-associated bloodstream infections. *Adv Exp Med Biol*. 2015;830:157-79. doi:10.1007/978-3-319-11038-7_10 6. Food and Drug Administration. Product Classification. Accessed October 2, 2023. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NZW> 7. 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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