DEFENCATH®
Taurolidine and Heparin Catheter Lock Solution

Limited Population

Frequently Asked Questions about **DefenCath**

What is DefenCath?

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

- A first-in-class CLS with taurolidine + heparin[1]
- Reduces the incidence of CRBSIs before infections can start, so you can protect the entire length of the lumen[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.

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.

Not actual size.

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.

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.

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

Q What is a CRBSI? How is it different from a CLABSI?

Although often used interchangeably, 'catheter-related bloodstream infection' (CRBSI) and 'central line-associated bloodstream infection' (CLABSI) have different meanings.[3]

CRBSI

CRBSI is a clinical definition used when diagnosing and treating patients, and requires specific laboratory testing that more throughly identifies the catheter as the source of infection. It is not typically used for surveillance purposes.[3] In the LOCK-IT-100 trial, the clinical adjudication commitee (CAC) defined CRBSIs using the following criteria:[1]

- ≥1 positive blood culture (other than for coagulase-negative staphylococci) from a peripheral site or either the arterial or venous catheter hub or the arterial or venous dialysis blood line, **and**
- A clinical suspicion of infection and no other apparent source of bloodstream infection

CLABSI

Surveillance definition used by the CDC defined as the recovery of a pathogen from:[4,5]

- **Blood culture** in a patient with a central line at the time of infection or within 48 hours before infection development
  - 1 blood culture for an organism not commonly present on skin
  - ≥2 blood cultures for an organism commonly present on skin
- Note: infection cannot be related to any other infection and must not have been present or incubating when the patient was admitted

Q Why should we aim to reduce the risk of CRBSIs for patients receiving HD?

Protecting the entire length of the lumen of the CVC is critical to reducing the risk of CRBSIs, yet there has been little advancement in the standard of care to help reduce infections among patients receiving HD through a CVC (HD-CVC).[6]

- Patients on HD have a 100-fold higher risk of methicillin-resistant *Staphylococcus aureus* bloodstream infection than the general population[7]
- HD-CVC patients who develop a CRBSI are 3 times more likely to die at 3 months than those without a CRBSI[8]
- CRBSIs in dialysis patients cost the US healthcare system ~$3.4 billion per year in hospitalization costs[9]

Not actual size.

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

- **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.

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

Q What distinguishes DefenCath from the options currently in use?

Heparin lock solutions

- Heparin, the current CLS standard of care, does not have any antimicrobial properties[13]
- DefenCath combines taurolidine, which possesses antimicrobial properties that reduces the risk of infections by killing or inhibiting the growth of bacteria and fungi, with heparin, an anticoagulant that aids in maintaining the patency of catheter lines[1,14]

Antibiotic lock solutions

- There are no FDA-approved antibiotic lock solutions available in the US
- Antibiotic lock solutions are compounded with high concentrations of broad-spectrum antibiotics that are used to treat infections[15,16]; antibiotic concentrations can vary and subtherapeutic exposure may lead to antibiotic resistance[13]
- DefenCath reduces the risk of CRBSIs before infections can start.[1] DefenCath demonstrates potent antimicrobial activity against gram-positive and gram-negative bacteria and fungi commonly associated with CRBSIs[1,2,14,17,18]

Q Who is the appropriate patient type for DefenCath?

DefenCath was studied in a broad range of adult patients with kidney failure receiving chronic HD-CVC, and is an option for all adult patients receiving chronic HD-CVC[1,2]

The following patients may require chronic HD-CVC:

- Patients with acute kidney injury (AKI) or end-stage renal disease (ESRD)[19,20]
- Patients with new or existing CVCs[2]
- Patients with tunneled or non-tunneled catheters[21]
- Patients with a previous episode of CRBSI[22]

Q How can DefenCath be used with commonly used HD-CVCs?

With refrigeration-free storage,[1] DefenCath is administered similarly to standard of care (heparin)[1,13]

- DefenCath is instilled into each catheter lumen at the conclusion of each HD session. DefenCath should be aspirated from the catheter and discarded prior to the initiation of the next HD session. If DefenCath cannot be aspirated, continue with standard of care CVC preparation and flush with normal saline. If a catheter malfunction is suspected, appropriate standard of care measures should be instituted.[1]
- DefenCath is **not** intended for systemic administration. Do **not** use DefenCath as a catheter lock flush product[1]

Please see full Prescribing Information for more information on dosage and administration.

IMPORTANT SAFETY INFORMATION (Cont'd)

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 Inc at 1-844-424-6345 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

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Protect the central line

DefenCath is the first and only FDA-approved catheter lock solution (CLS) proven to significantly reduce the risk of CRBSIs before infections can start, with no known antimicrobial resistance.[1,2,14,23,24]

Download the Prescribing Information for DefenCath

IMPORTANT SAFETY INFORMATION (Cont'd)

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 the full Prescribing Information.

AKI=acute kidney injury; CLABSI=central line-associated bloodstream infection; CLS=catheter lock solution; CRBSI=catheter-related bloodstream infection; CVC=central venous catheter; ESRD=end-stage renal disease; FDA=US Food and Drug Administration; HD=hemodialysis.

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;18(11):1446-1455. **3.** Centers for Disease Control and Prevention. Guidelines for the Prevention of Intravascular Catheter-Related Infections. Accessed November 6, 2023. https://www.cdc.gov/infectioncontrol/guidelines/bsi/background/terminology.html **4.** Haddadin Y, et al. Central Line Associated Blood Stream Infections. [Updated 2022 Nov 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430891/. **5.** Wright MO, et al. *Am J Infect Control.* 2018;46(5):577-578. **6.** Himmelfarb J, Vanholder R, Mehrotra R, Tonelli M. The current and future landscape of dialysis. *Nat Rev Nephrol.* 2020;16(10):573-585. **7.** Centers for Disease Control and Prevention (CDC). Vital Signs: Health disparities in hemodialysis-associated Staphylococcus aureus bloodstream infections — United States, 2017–2020. *MMWR Morb Mortal Wkly Rep.* 2023;72(6):153-159. **8.** Massey K, Rajagopalan K, Rajagopalan S, Grossman A, Chew P. Catheter-related bloodstream infections incidence and associated mortality risk: analysis of merged United States Renal Data System-Medicare claims. Poster presented at ASN Kidney Week 2021; November 4-7, 2021; San Diego, CA. **9.** Market research commissioned by CorMedix from a third-party firm. **10.** O'Grady NP. Prevention of central line-associated bloodstream infections. *N Engl J Med.* 2023;389(12):1121-1131. **11.** Pursuit Vascular, Inc. ClearGuard [510(k) Summary]. US Food and Drug Administration website. https://www.accessdata.fda.gov/cdrh_docs/pdf13/k131060.pdf. Revised Dec 2013. Accessed Mar 2024. **12.** Nguyen DB, Shugart A, Lines C, et al. National Healthcare Safety Network (NHSN) Dialysis Event Surveillance Report for 2014. *Clin J Am Soc Nephrol.* 2017;12(7):1139-1146. **13.** 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. **14.** Data on file, CorMedix Inc. **15.** Almeida BM, Moreno DH, Vasconcelos V, Cacione DG. Interventions for treating catheter-related bloodstream infections in people receiving maintenance haemodialysis. *Cochrane Database Syst Rev.* 2022;4(4):CD013554. **16.** Justo JA, Bookstaver PB. Antibiotic lock therapy: review of technique and logistical challenges. *Infect Drug Resist.* 2014;7:343-363. **17.** 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. **18.** Shah H, Bosch W, Thompson KM, Hellinger WC. Intravascular catheter-related bloodstream infection. *Neurohospitalist.* 2013;3(3):144-151. **19.** Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group. KDIGO clinical practice guideline for acute kidney injury. *Kidney Int Suppl.* 2012;2(1):1–138. **20.** Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. KDIGO 2024 clinical practice guideline for the evaluation and management of chronic kidney disease. *Kidney Int Suppl.* 2024;105(4S): S117–S314. **21.** Sohail MA, Vachharajani TJ, Anvari E. Central venous catheters for hemodialysis-the myth and the evidence. *Kidney Int Rep.* 2021 Oct 11;6(12):2958-2968. **22.** Miller LM, Clark E, Dipchand C, et al; Canadian Society of Nephrology Vascular Access Work Group. Hemodialysis tunneled catheter-related infections. *Can J Kidney Health Dis.* 2016;3:2054358116669129. **23.** Torres-Viera C, Thauvin-Eliopoulos C, Souli M, et al. Activities of taurolidine in vitro and in experimental enterococcal endocarditis. *Antimicrob Agents Chemother.* 2000;44(6):1720-1724. **24.** Liu H, Liu H, Deng J, Chen L, Yuan L, Wu Y. Preventing catheter-related bacteremia with taurolidine- citrate catheter locks: a systematic review and meta-analysis. *Blood Purif.* 2014;37(3):179-187.

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