DEFENCATH®
Taurolidine and Heparin Catheter Lock Solution
Limited Population

ORDERING DEFENCATH®

PRODUCT INFORMATION

National Drug Code (NDC)
Carton – 10 vial pack — 10 digit: 72990-103-10 | 11 digit: 72990-0103-10

Dosage Forms and Strengths
DefenCath catheter lock solution (CLS) is available in:
- 3 mL of CLS in a single-dose vial containing taurolidine 40.5 mg/3 mL (13.5 mg/mL), and heparin 3,000 USP Units/3 mL (1,000 USP Units/mL)

How Supplied
Each vial contains a sterile, preservative-free, clear aqueous-based solution for instillation in central venous catheters. Each carton contains 10 single-dose vials.

DEFENCATH DISTRIBUTOR ORDERING INFORMATION

	CardinalHealth™ **Cardinal Health™ Specialty Pharmaceutical Distribution** Customer Service: 855-855-0708 https://pdlogin.cardinalhealth.com/signin	McKESSON **McKesson Specialty Health** Customer Service: 800-482-6700 https://mscs.mckesson.com	
Inpatient Procurement Inpatient Hospitals Hospital Owned Entities	CARDINAL SD (IP) CIN: 5909569	Plasma and Biologics Item number: 2989606	
Outpatient Procurement Dialysis Clinics Outpatient Hospitals Vascular Surgery Centers Ambulatory Surgery Centers Office-Based Laboratories Infusion Centers Specialty Pharmacies	CARDINAL SD (OP) CIN: 5921259	Plasma and Biologics Item number: 2989606	**Non-Hospital Owned Entities** Specialty Care Distribution Item number: 5018785
Dialysis Organizations Dialysis Centers	Metro Medical CIN: 729901	Plasma and Biologics Item number: 2989606	Specialty Care Distribution Item number: 5018785
Veterans Affairs VA Medical Centers VA Dialysis Centers	**Available, Not Preferred** CARDINAL SD (IP) CIN: 5909569	**Preferred** Plasma and Biologics Item number: 2989606	

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.

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 full Prescribing Information.

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ABOUT DEFENCATH®

INDICATIONS AND USAGE

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DOSAGE AND ADMINISTRATION

- DefenCath is for instillation into CVCs only
- DefenCath is **not** intended for systemic administration
- Do **not** use DefenCath as a catheter lock flush product
- Withdraw a sufficient volume of DefenCath CLS from the vial using a sterile needle and syringe to fill the catheter lumen
- Use 3 mL single-dose vial to instill DefenCath into each catheter lumen at the conclusion of each HD session
- DefenCath should be aspirated from the catheter and discarded. 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.
- Discard any unused portion of DefenCath remaining in the vial

STORAGE AND HANDLING

DefenCath vials must be stored at a controlled room temperature of 20°C to 25°C (68°F to 77°F); excursions are permitted from 15°C to 30°C (59°F to 86°F). Do not freeze. DefenCath vials must be stored in the commercial carton, prior to the instillation in CVCs.

PRODUCT RETURNS

Before attempting to return this product to CorMedix, please obtain a Returned Material Authorization (RMA) label. You may email this request to the CorMedix Returned Goods Department at GMB-SPS-ReturnRequests@cordlogistics.com or fax the request to 614-652-0271.

Alternatively, for purchases made through a distributor, please contact the distributor directly.

For more information, please see Defencath full Prescribing Information.

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 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 additional Important Safety Information throughout and full Prescribing Information.

FDA=US Food and Drug Administration

Reference: DefenCath (taurolidine and heparin) [prescribing information]. Berkeley Heights, NJ: CorMedix Inc; 2024.

CorMedix®