

CE 0476 D.B.M. C-LOCK 46,7%

STERILE SODIUM CITRATE 46,7%

EN

IT

FR

DE

ES

PT

PL

CE 0476 D.B.M. C-LOCK 46,7%

SODIUM CITRATE 46,7% STERILE

CE 0476 D.B.M. C-LOCK 46,7%

SOLUZIONE "LOCK" di sodio citrato al 46,7% sterile per catetere intravenoso

Sterile - Senza lattice - Monouso

IT

FR

DE

ES

PT

PL

CE 0476 D.B.M. C-LOCK 46,7%

CITRATO DI SODIO 46,7% STERILE

DE

ES

PT

PL

CE 0476 D.B.M. C-LOCK 46,7%

SODIO CITRATO 46,7% ESTÉRIL

ES

PT

PL

CE 0476 D.B.M. C-LOCK 46,7%

JALOWY CYTRYNIAN SODU 46,7%

PL

ES

PT

CE 0476 D.B.M. C-LOCK 46,7%

CYTRYNIANI SODU 46,7% JAWŁOWY ROZWÓJ "LOCK" DO OZNÓWKI DODZYCHN.

PL

ES

PT

CE 0476 D.B.M. C-LOCK 46,7%

CYTRYNIA SODU 46,7% JAWŁOWY ROZWÓJ "LOCK" DO OZNÓWKI DODZYCHN.

PL

ES

PT

CE 0476 D.B.M. C-LOCK 46,7%

CYTRYNIA SODU 46,7% JAWŁOWY ROZWÓJ "LOCK" DO OZNÓWKI DODZYCHN.

PL

ES

PT

CE 0476 D.B.M. C-LOCK 46,7%

CYTRYNIA SODU 46,7% JAWŁOWY ROZWÓJ "LOCK" DO OZNÓWKI DODZYCHN.

PL

ES

PT

CE 0476 D.B.M. C-LOCK 46,7%

CYTRYNIA SODU 46,7% JAWŁOWY ROZWÓJ "LOCK" DO OZNÓWKI DODZYCHN.

PL

ES

PT

CE 0476 D.B.M. C-LOCK 46,7%

CYTRYNIA SODU 46,7% JAWŁOWY ROZWÓJ "LOCK" DO OZNÓWKI DODZYCHN.

PL

ES

PT

PL

QUALITATIVE AND QUANTITATIVE COMPOSITION
SODIUM CITRATE TRIBASIC DIHYDRATE 46,7%
Excipients: ACID CITRIC MONOHYDRATE q.s. to pH 6,7 - WFI q.s. to 1000 mL.

DEVICE TYPE

Sterile, pyrogen-free, ready-to-use Medical Device - Class IIb.

Medical Device not subject to a medical prescription

PACKAGING
PCE14KA1: 3 ml, disposable pre-filled syringe, filled to 2,5 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14KA2: 3 ml, disposable pre-filled syringe, filled to 2,5 mL, with Luer Lock adapter,twin packaged in a PET/PP paper pouch.
PCE14LA1: 3 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA2: 3 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, twin packaged in a PET/PP paper pouch.
PCE14LA3: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA4: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA5: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA6: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA7: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA8: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA9: 5 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA10: 10 ml, disposable pre-filled syringe, filled to 3 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA11: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA12: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA13: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA14: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA15: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA16: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA17: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA18: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA19: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA20: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA21: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA22: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA23: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

PCE14LA24: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.
PCE14LA25: 10 ml, disposable pre-filled syringe, filled to 10 mL, with Luer Lock adapter, individually packaged in a PET/PP paper pouch.

Only the contents and the outside of the syringe are sterile with all types of packaging. The syringe and the product are moist-heat sterilized in autoclave.

The volume reported on the label refers to the filling volume of the syringe. The graduated scale reported on the label of the primary packaging (syringe) has no measuring function.

INTENDED USE

The device is intended for the safe practice of vascular access. Its function is to maintain the central venous catheters (CVC) placed in the interdialytic interval, also performing an anticoagulant function. The presence of citrate requires a coexisting action for the calcium ions in the blood and tissues, making them not available for the coagulative cascade. Therefore, this solution eliminates the risks of systemic anticoagulation connected with the use of heparin as a lock solution and ensures total safety and handiness thanks to the ready-to-use pre-filled syringes.

D.B.M. C-Lock 46,7% ensures a full antimicrobial effect and reduces biofilm formation in vascular access devices by binding and removing calcium and magnesium ions from the surrounding environment.

By adopting an aseptic procedure, D.B.M. C-Lock 46,7% can be used on the sterile field.

SPECIAL INSTRUCTIONS AND PRECAUTIONARY MEASURES

• To be used only by suitably trained medical staff who are capable to take all necessary precautions.

• Do not administer intravascularly.

• Do not use the product for purposes other than its intended use.

• Do not use the product if the packaging is open or damaged, if the syringe is not perfectly intact or if the cap is so damaged that the syringe leaks.

• Do not use the product if it is not colorless or if it contains particulate matter.

• Once opened, the device must be used immediately and disposed of after use.

• Single-use only. Dispose of any partially used product, the reuse of which may cause cross contamination between patient and operator.

• Do not re-sterilize.

• Do not let air enter the syringe and do not allow it to get trapped in the fluid path. Use only with compatible Luer Lock adapters.

• The vascular access device is not adequately sealed, close form sealing in lumen.

• Do not use an injection volume greater than the lumen priming volume specified by the manufacturer of the vascular access device.

• Should blood be taken through the catheter, consider that even minimal residues of sodium citrate can lead to incorrect closure of the catheter.

• Keep off reach and sight of children.

CONTRAINDICATIONS AND SIDE EFFECTS

If a portion of sodium citrate, which is inside the catheter during the interdialytic interval, inadvertently gets into the patient's bloodstream, chelation of calcium ions may occur, resulting in hypocalcaemia and hypotension, as well as possible arrhythmias or even death.

INSTRUCTIONS FOR USE

Despite its use on the sterile field.

In order to ensure a sterile application of the product, the health-care worker must comply with the procedures provided for by the health-care institution, applying an aseptic technique to the entire procedure.

Check the validity of the expiry date on the sealing side of the pouch.

Open the pouch and take out the syringe. Check the correct position of the syringe cap, the transparency of the solution and the absence of any residual air bubbles.

Close the syringe with a new sterile cap.

Wash the lumens of each catheter, using a sterile isotonic solution (Sodium Chloride 0,9%), to clean up any residual haematic components from previous operations.

Remove the rubber stopper to remove the rubber seal.

Close the syringe and make sure that no contact remains.

Connect the syringe to the vascular access device while taking care to avoid any contact contamination with the Luer Lock connection.

Do not inject the amount exceeding the volume of the catheter.

After use, dispose of the empty syringe and any unused solution volumes in accordance with the national regulations in force.

SHELF-LIFE

3 years in an intact pouch.

STORAGE

Store the syringes tightly sealed, away from direct light and heat sources, at a temperature between + 5 °C and + 30 °C. Do not freeze. The storage time refers to the product in its intact packaging and correctly stored. Do not use the Medical Device after the expiration date.

SYMBOLS USED ON THE LABEL



Do not reuse - Disposable



Manufacturer



Fabricante



Hersteller



Fabricante



Artikelnummer



Lote de producción



Data de validade



Data de vencimiento



Ne pas utiliser si l'emballage est ouvert ou déformé



Limites de température pour la stockage



Tenere lontano da luce e fonti di calore



Proteggere dall'umidità



CE 0476



D.B.M. Srl



T +39 0342 771613 - info@dbmitalia.it - www.dbmitalia.it



CE 0476



D.B.M. Srl



T +39 0342 771613 - info@db

