

TECHNICAL DATA SHEET

MD042 dialysis solution for Continuous Renal Replacement Therapy



INDICATION FOR USE

Intended for use as a dialysis solution in Continuous Renal Replacement Therapy.

DESCRIPTION

MD042 is a bicarbonate based dialysis solution packaged in a ready to mix, sterile, non-pyrogenic, two-chambered solution container system. One chamber contains the acidic solution and one chamber contains the basic solution. At the point of use, the membrane between the two chambers is broken, and the acidic and basic solutions are mixed to form the final ionic composition of the solution to be used in the Continuous Renal Replacement Therapy (CRRT) treatment.

The MD042 solution is offered in bi-chambered volumes of 500+1500 ml. The chemical composition of the final solution is located in the table below.

FORMULATION

SOLUTION A	
	g / L
$C_6H_{12}O_6 \cdot H_2O$	4.40
KCl	0.75
$CaCl_2 \cdot 2H_2O$	0.88
$MgCl_2 \cdot 6H_2O$	0.61
HCl 37%	1.18
WFI q.s.	1000 mL

SOLUTION B	
	g / L
NaCl	8.18
$NaHCO_3$	3.92
WFI q.s.	1000 mL

MD042	
Ca^{2+}	1.5 mmol/L
HCO_3^-	32 mmol/L
K^+	2.5 mmol/L
PO_4^{3-}	0
Mg_2^+	0.75 mmol/L
Na^+	140 mmol/L
Cl ⁻	115 mmol/L
$C_6H_{12}O_6$	5.55 mmol/L
Theoretical Osmolarity	297.3 mOsm/L

PACKAGING SPECIFICATIONS

A. Primary Packaging:

Flexible bag of non-PVC material (Nexcel™ film). It is a non-reusable, two-compartment bag; 500 mL for Solution A, 1500 mL for Solution B, to be mixed before use.

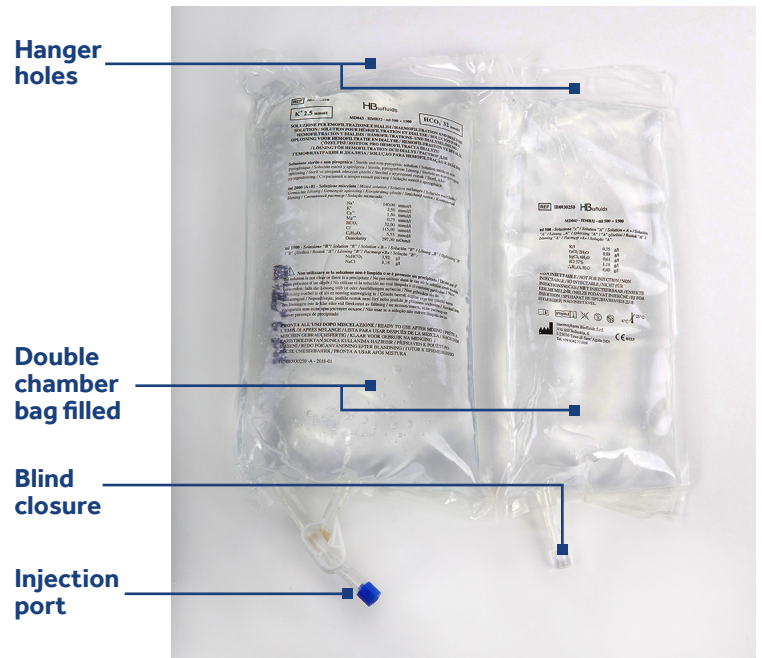
The double bag is equipped with three different systems: breakable cone, blind closure, and injection port (latex-free rubber).

B. Secondary Packaging:

Vacuum packaging with double-layer barrier film PP/PA.

C. UOM Packaging:

Cardboard box containing four (4) bags of 500 mL + 1500 mL bi-chamber bags.



ORDERING INFORMATION

CAPITAL		
Product Code	Description	UOM
IB7010250	CARPEDIEM™ 110-120 V	1 EA
IB7000020	BIEGLER BW685 (110-120 V)	1 EA

DISPOSABLES/CONSUMABLES		
IB0595570	BL 250 Hemofiltration/Hemodialysis Kit 015 for CARPEDIEM™	4/CT
IB0595580	BL 250 Hemofiltration/Hemodialysis Kit 025 for CARPEDIEM™	4/CT
MD042	HMB32 Double Chamber 1500+500 ml	4/CT
IB0507009	Carpediem™ 3 liter Waste Bag	20/CT
IB0950805	10 cc Syringe	100/CT
IB0957081	Warmer Extension Set - Tubing	20/CT

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