

Technical Data Sheet

Bicompartmental dialysis solution for continuous renal replacement therapy

Description

This bag is a bicarbonate-based dialysis solution packaged in a ready to mix, sterile, non-pyrogenic, bicompartmental solution container system. One chamber contains the acid solution and one chamber contains the basic solution. At the point of use, the membrane between the two chambers is opened, and the acid 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 solution is offered in bicompartmental volumes of 500 + 1500 mL. The chemical composition of the final solution is reported in the table below.



Figure 1. Dialysate bag

Formulation

Solution A	(g / L)
$C_6H_{12}O_6H_2O$	4.40
KCl	0.75
$CaCl_2 \cdot 2H_2O$	0.88
$MgCl_2 \cdot 6H_2O$	0.61
HCl 37%	1.18

Solution B	(g / L)
NaCl	8.18
$NaHCO_3$	3.92

Final Solution	
Ca^{2+}	1.5 mmol / L
HCO_3^-	32 mmol / L
K^+	2.5 mmol / L
PO_4^{3-}	0 mmol / L
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	297.30 mOsm / L

Intended Use

The solution is indicated for use as a dialysis solution in Continuous Renal Replacement Therapy.

Sterilization method and validity

Sterilization: Moist heat. Shelf life: 18 months

Packaging Specifications

A. Primary Packaging

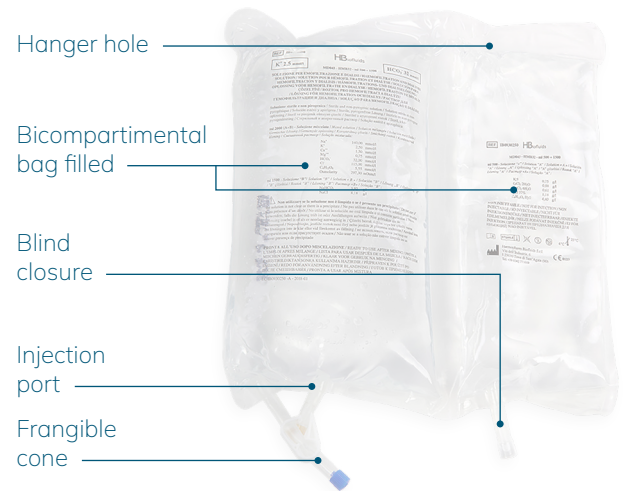
Flexible bag of non-PVC material (Nexcel™* film). It is a non-reusable, bicompartimental bag; 500 mL for Solution A, 1500 mL for Solution B, to be mixed before use. The bicompartimental bag is equipped with three different systems: frangible cone, blind closure, and injection port (latex-free). The tube equipped with the frangible cone connector is also equipped with a clamp.

B. Secondary Packaging

Vacuum packaging of PP / PA film.

C. UOM Packaging

Cardboard box containing four (4) bags of 500 mL + 1500 mL bicompartimental bags.



Storage and Disposal Conditions

Storage conditions: Do not store below 4 degrees Celsius or above 25 degrees Celsius. Keep away from direct light, in a dry and clean place.

Disposal: Do not dispose of the container after use. The portions of unused solution and empty containers shall be discarded and disposed.

Codes Available

CFN	Model	Notes	UOM
IB0930250	MD043 – HMB32 mL 500 + 1500	Available labeling languages: Italian, English, French, Spanish, German, Dutch, Turkish, Czech, Swedish, Russian, Portuguese.	4 / CT
MD087	HMB32 mL 500 + 1500	Available labeling languages: English, Bulgarian, Greek, Indonesian, Lithuanian, Polish, Serbian, Ukraine, Croatian	4 / CT

HMB32 Haemofiltration and dialysis solution is a non-active, non-invasive, class IIb medical device CE0123 manufactured by Haemopharm Biofluids S.r.l. Important: Please refer to the package inserts for complete instructions, contraindications, warnings and precautions in your respective geography.

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