

multi**Plus** K⁺ 2 mmol/L

Instructions for use

Intended use

multiPlus is a dialysis solution for continuous veno-venous haemodialysis (CVVHD). multiPlus has to be used on a machine intended for CVVHD treatment that ensures volume balance compliance.

Contraindications

- Dialysis solution should not be used on patients with hyperphosphataemia.
- multiPlus must not be infused intravenously or into the extracorporeal circuit.

Composition

multiPlus is supplied as a double chamber bag with a total volume of 5,000 mL. The ready-to-use dialysis fluid is obtained by mixing both compartments immediately prior to the application. The small compartment contains 250 mL of a solution (with a pH of about 2.7) with 30 mmol/L Ca⁺⁺, 15 mmol/L Mg⁺⁺, 20 mmol/L K⁺, 112 mmol/L Cl⁻ and 111 mmol/L glucose. The large compartment contains 4750 mL of a solution with 147.37 mmol/L Na⁺, 1.053 mmol/L K⁺, 110.42 mmol/L Cl⁻, 36.95 mmol/L HCO₃⁻ and 1.053 mmol/L H₂PO₄⁻.

The ready-to-use dialysis solution contains:

Sodium chloride	6.136	g/L
Sodium bicarbonate	2.940	g/L
Potassium dihydrogen phosphate	0.1361	g/L
Potassium chloride	0.07455	g/L
Calcium chloride dihydrate	0.2205	g/L
Magnesium chloride hexahydrate	0.1525	g/L
Glucose monohydrate	1.100	g/L

Other constituents: Water for injektion, hydrochloric acid 25%

The concentrations of the ions and of glucose in the ready-to-use dialysis fluid are:

Na ⁺	140	mmol/L
K ⁺	2.0	mmol/L
Ca ⁺⁺	1.5	mmol/L
Mg ⁺⁺	0.75	mmol/L
Cl ⁻	110.5	mmol/L
HCO ₃ ⁻	35	mmol/L
H ₂ PO ₄ ⁻	1.0	mmol/L
Glucose, anhydrous	1.0	g/L
pH ≈	7.4	
theoretical osmolarity	296	mOsm/L

Method of application

multiPlus is a dialysis solution that is used for CVVHD treatment. Prior to and during treatment checking of serum electrolytes (Na, K, Ca, Mg, inorganic phosphate), the acid-base status and the concentration of glucose have to be done at regular intervals. As multiPlus contains phosphate performing CVVHD therapies with this solution should not require a separate phosphate substitution in most cases.

Due to the risk of low phosphate elimination multiPlus should not be used on patients with hyperphosphataemia.

Dose of the continuous haemodialysis

If not clinically contra-indicated the required efficacy of the continuous haemodialysis treatment is achieved with an application of 1,500 - 2,500 mL/h dialysis solution in adults, depending on body weight. There is no experience with the treatment of children.

Handling

For convenient handling the bag should be at room temperature.

Opening of the overwrapping

The double-chamber bag containing the dialysis solution must only be taken out of its overwrapping immediately prior to use. Before opening, the overwrapping must be checked for damage. Bags with damaged overwrapping should be discarded.

Mixing of both compartments

Both compartments must be mixed immediately prior to the use of the dialysis solution.

After mixing both compartments, it must be checked, that the peel seam is completely open, that the solution is clear and colourless and that the bag is not leaking.

multiPlus must be used within 48 h after mixing.

Connection of the bag to the extracorporeal circuit

After mixing both compartments, the bag with the dialysis solution is connected to the dialysate circuit according to the instructions for use of the chosen device for continuous renal replacement therapy. Contamination of the dialysis solution or of any parts in contact with the dialysis solution must be avoided. A bag of multiPlus, which has been disconnected from the dialysate circuit, should be discarded.

Prior to application, multiPlus should be warmed to approximately body temperature to prevent any significant drop in the patient's body temperature.

Notes

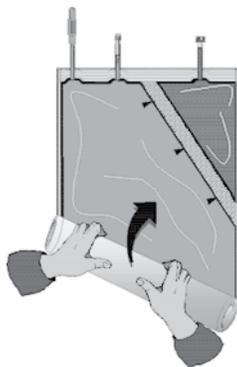
- Dialysis fluid for CVVHD in a double-chamber bag.
- **Do not use prior to the mixing of both compartments.**
- **Dialysis solution must be used within 48 h after mixing.**
- Solution is not to be used for intravenous infusion.
- Use only if solution is clear and container not damaged.
- Do not apply the dialysis solution in patients with hyperphosphataemia.
- Sterilized using steam.
- Free of bacterial endotoxins.
- Do not store below +4 °C or above +25 °C.
- Expiry date: See information on the label.
- Do not re-use.

A)



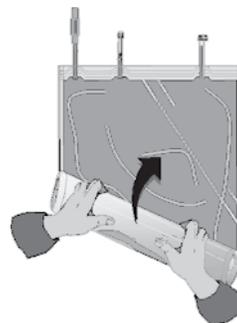
Unfold the small compartment.

B)



Roll up the solution bag starting from the corner opposite the small compartment ...

C)



... until the peel seam between both compartments has opened along its entire length and the solutions from both compartments are mixed.



Legal Manufacturer:



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