ACCUSOL K+ 0 – ACCUSOL K+ 2 – ACCUSOL K+ 4, 5000 mL

INSTRUCTIONS FOR USE

ENG

Please read carefully before use

INDICATIONS

ACCUSOL is a dialysis solution intended to be used during continuous veno-venous hemodialysis therapies and is prescribed to patients suffering from acute kidney injury. ACCUSOL K+ 0 and ACCUSOL K+ 2 contain respectively 0 and 2 mmol/L potassium, these are lower concentrations than in plasma; they are intended to be used for patients with hyperkalaemia. ACCUSOL must be used by skilled personnel with supervision of nephrologist or intensivist. A delivered dose of 20–25 mL/kg/hr is recommended for CRRT in AKI to achieve an effective therapy depending on bodyweight. This may require a higher prescription of effluent volume. These fluid volume recommendations may be adjusted by the prescribing physician according to the patient's clinical status. There are no data on the use of ACCUSOL with the treatment of children or during pregnancy and lactation. ACCUSOL should only be administered to children, and pregnant and lactating women if clearly needed. ACCUSOL increase the removal of metabolic waste products from the blood and helps to manage the serum electrolytes and/or fluid imbalances.

COMPOSITION

	ACCUSOL K+ 0	ACCUSOL K+ 2	ACCUSOL K+ 4
LARGE COMPARTMENT (g/L)			
$CaCl_2$ 2H2O	0.343	0.343	0.343
$MgCl_2$.6H2O	0.136	0.136	0.136
NaCl	7.52	7.52	7.52
KCl	0	0.199	0.398
Glucosum anhydricum	0	1.33	1.33
SMALL COMPARTMENT (g/L)			
$NaHCO_3$	13.4	13.4	13.4
READY TO USE DIALYSIS SOLUTION (g/L)			
NaCl	6.12	6.12	6.12
$CaCl_2$ 2H2O	0.257	0.257	0.257
$MgCl_2$ 6H2O	0.102	0.102	0.102
KCl	0	0.149	0.298
$NaHCO_3$	2.94	2.94	2.94
Glucosum anhydricum	0	1.0	1.0
ELECTROLYTES COMPOSITION IN THE READY TO USE DIALYSIS SOLUTION (mmol/L)			
Na^+	140	140	140
K^+	**0**	**2**	**4**
Ca^{2+}	1.75	1.75	1.75
Mg^{2+}	0,5	0,5	0,5
Cl^-	109.3	111.3	113.3
HCO_3^-	35	35	35
Glucosum anhydricum	**0**	**5.55**	**5.55**
Water for injections to 5000 mL for the ready to use dialysis solution			

ACCUSOL is a bicarbonate-based lactate-free solution.

CONTRA-INDICATIONS

There are no contra-indications.The choice of the formulation and therefore the concentration of the electrolytes must be selected under medical prescription and adequate with the hydro-electrolytic balance of the patient. Please refer to the "warning" section for special precautions.

UNDESIRABLE SIDE-EFFECTS

No undesirable side-effects associated specifically with ACCUSOL are currently known. Possible undesirable side-effects may not all be due to the treatment:

- Metabolic and nutrition side-effects (Electrolyte imbalances, acid-base imbalance, fluid imbalance, hypoglycaemia, hypophosphataemia)
- Vascular side-effects (Hypotension, hypertension, bleeding disorder)
- Gastrointestinal side-effects (Nausea, vomiting)
- Musculoskeletal and connective tissue side-effects (muscle cramps)
- Infection, anaphylactic reaction
- Blood clotting
- Hypothermia

WARNINGS AND PRECAUTIONS FOR USE

- **Not to be used as substitution solution. Not for direct intravenous infusion;**
- This solution must be used in a clinical environment and by skilled personnel with supervision of nephrologist or intensivist only; ACCUSOL K+ 0 does not contain potassium nor glucose;
- During the treatment, the haemodynamic (cardiac and vascular parameters), the hydro-electrolytic balance (water and electrolytes) and the acid-base balance of the patient must be controlled on a regular basis;
- Particular attention must be given to the kalaemia of the patient, especially when using ACCUSOL K+ 0 and ACCUSOL K+ 2 as they have a lower concentration of potassium than plasma;
- Additives should be added through the injection site, after disinfection of the site and before opening of the long-seal (interchamber seal); Compatibility must be checked before admixture. Use the solution immediately after the addition of additives;
- The two chambers are separated by a long-seal (interchamber seal). Prior to any connection to any line, the two chambers of ACCUSOL solutions must first be mixed by activating the long-seal (interchamber seal), followed by the activation of the short seal near the access port.
- Use within 24 hours after removal of the overpouch and mixing;
- Use only if the solution is perfectly clear and if the container is not damaged;
- Use only if the connector is not damaged, if no leakage is observed, if the cap on the Luer connector is in place, and if the long-seal (interchamber seal) or the short seal are not open at any point;
- Use ACCUSOL only with Aquarius devices;
- Use only with compatible Luer connectors;
- This bag is for single use only. Discard unused fluid. Reuse of residual solution may affect the sterility or pyrogenicity of the product;
- For the duration of therapy, the dialysate line should be regularly inspected to verify that the solution in the tubing is clear. If particles are observed, the ACCUSOL solution and CRRT tubing lines must be replaced immediately and the patient monitored;
- Discard the device according to your local regulations after use, do not use it as an effluent collection bag;
- Expiry date refers to the product correctly stored and in its original packing;
- Do not use the product after date of expiry;
- To prevent accidents, store carton boxes at a low level.

INSTRUCTIONS FOR USE

Manipulations must be performed under standard aseptic conditions.

- Place the bag flat with the connector facing towards you;
- Check solution formulation and expiry date;
- Open the overpouch;
- Check solution clarity and connector integrity; if damaged, discard the bag;
- Check the long-seal (interchamber seal) or the short seal are not open at any point by pressing firmly on the upper, then lower chamber using the palm of your hands. If the long-seal (interchamber seal) or the short seal are open at any point, or if there is a leak, discard the bag;
- Inject additives before opening the long-seal if applicable;
- Open the long-seal (interchamber seal) to mix the two solutions. Ensure that the long-seal (interchamber seal) is completely activated and the two solutions are completely mixed. Then open the short seal (seal near access port) to allow the administration of the mixed solution.
- Hang the bag on the machine;
- Remove the cap of the Luer connector and connect to the dialysate line;
- Close the wings of the connector completely (make sure the wings are firmly closed).

REPORTING INCIDENTS

Reports any incidents to Nikkiso Belgium bv by phone +32 (0)16 781 770 or by email complaint@nikkisomedical.com and to your local health authorities.

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	Do not re-use
	Non-pyrogenic
	Sterilized using steam or dry heat
	Lower limit of temperature
	Manufacturer
	Medical device
	Patient information website
	Single sterile barrier system with protective packaging outside
	Catalogue number
	Consult instructions for use or consult electronic instructions for use
	Batch code
	Use-by date
	Date of manufacture
	Caution

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