Vantive

Hemosol

CRRT SOLUTION

HEMOSOL BO

Bicarbonate-buffered solution for haemodialysis and haemofiltration

Powered By **PrisMax** and **Prismaflex**

HEMOSOL B0

Abbreviated Summary of Product Characteristics

This abbreviated summary of product characteristics (SPC) is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, always consult your country-specific SPC or package leaflet.

NAME OF THE MEDICINAL PRODUCT

Hemosol B0 solution for haemodialysis/haemofiltration

QUALITATIVE AND QUANTITATIVE COMPOSITION

Hemosol B0 consists of a two compartment polyolefin bag containing the electrolyte solution in the small compartment (compartment A) and the buffer solution in the large compartment (compartment B).

BEFORE RECONSTITUTION

1000 ml of electrolyte solution small compartment (A) contains:	
Active substances:	
Calcium chloride, $2H_2O$	5.145 g
Magnesium chloride, $6H_2O$	2.033 g
Lactic acid	5.4 g
1000 ml of buffer solution large compartment (B) contains:	
Active substances:	
Sodium hydrogen carbonate	3.09 g
Sodium chloride	6.45 g

AFTER RECONSTITUTION

The small and the large compartments are mixed to give one reconstituted solution whose ionic composition is:

		mmol/l	mEq/l
Calcium	Ca^{2+}	1.75	3.50
Magnesium	Mg^{2+}	0.5	1.0
Sodium	Na^{+}	140	140
Chloride	Cl^{-}	109.5	109.5
Hydrogen carbonate	HCO_3^{-}	32	32
Lactate	$C_3H_5O_3^{-}$	3	3

Theoretical osmolarity: 287 mOsm/l
For the full list of excipients, see the full SPC.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

As substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis for acute renal failure in adult and children of all ages.

CONTRAINDICATIONS

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 of the full SPC.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Warnings:
The substitution solution **Hemosol** B0 is potassium-free. The serum potassium concentration must be monitored before and during hemofiltration and/or hemodialysis.

The electrolyte solution **must** be mixed with the buffer solution **before use** to obtain the final solution suitable for haemofiltration/haemodiafiltration/continuous haemodialysis.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE (continued)

Use only with appropriate extracorporeal renal replacement equipment.

Because the solution contains no glucose, administration may lead to hypoglycemia. Blood glucose levels should be monitored regularly.

Hemosol B0 contains hydrogen carbonate (bicarbonate), and lactate (a hydrogen carbonate precursor) which can influence the patient's acid-base balance. If metabolic alkalosis develops or worsens during therapy with the solution, the administration rate may need to be decreased, or the administration stopped.

The use of contaminated haemofiltration solution may cause sepsis, shock and fatal conditions.

Precautions for use:
Hemosol B0 may be warmed to 37°C to enhance patient comfort. Warming of the solution prior to use should be done before reconstitution with dry heat only. Solutions should not be heated in water or in a microwave oven. The solution should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact.

Before and during treatment, electrolyte and acid-base balance should be closely monitored throughout the procedure. Phosphate up to 1.2 mmol/l may be added to the solution. If potassium phosphate is added, the total potassium concentration should not exceed 4 mEq/l (4 mmol/l). Potassium supplement might be necessary.

The patient's hemodynamic status and fluid balance should be monitored throughout the procedure and corrected as needed.

Paediatric population:
There are no specific warnings and precautions when using this medicine for children.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy and breastfeeding:
No effects during pregnancy or on the breast-fed newborn/infant are anticipated. There is no report on **Hemosol** B0 during pregnancy or lactation but literature on renal replacement therapy during acute kidney injury does not suggest risks associated with solutions. The prescriber should consider the benefit/risk relationship before administering **Hemosol** B0 to pregnant or breast feeding women.

Fertility:
There are no clinical data on fertility. However, no effects on fertility are anticipated.

UNDESIRABLE EFFECTS

The following undesirable effects are reported from post-marketing experience.

Undesirable effects are (frequency unknown): electrolyte imbalances (e.g., hypophosphataemia, hypokalaemia), acid-base balance disorders, fluid imbalance, hypotension, nausea, vomiting, muscle spasms.

Special attention must be taken for patients with hypokalaemia as this solution is potassium-free (see section 4.4 of the full SPC).

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via their national reporting system.

For posology, incompatibilities, interactions, overdosage, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription.

March 2023

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