Baxter Healthcare Distribution Ltd
34 Jerusalem st Ra'anana entrance B
Israel
Tel: 972-545656441

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רופא/ה, רוקח/ת נכבד/ה,

הנדון: Hemosol B0 – המוסול B0

מרכיבים פעילים:

Calcium Chloride Dihydrate (electrolyte solution)
Magnesium Chloride Hexahydrate (electrolyte solution)
Lactic Acid (electrolyte solution)
Sodium Chloride (buffer solution)
Sodium Carbonate Hydrogen (buffer solution)

צורת מינון:

Solution for haemofiltration

התוויות מאושרות:

As substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis for acute renal failure.

חברת בקסטר אספקת שירותי בריאות בע"מ מבקשת להודיעכם על העדכונים הבאים בעלון לרופא של התכשיר:

בהתאם לאישור משרד הבריאות עודכן משטר המינון של התכשיר על פי עלון האסמכתא האנגלי, וכן עודכנו סעיפים נוספים בעלון כולל החמרות.
ההחמרות מסומנות באמצעות קו תחתי, שמשמעותו היא תוספת מידע הקשור להחמרה.

4.2 Posology and method of administration

Posology:

The rate at which Hemosol B0 is administered depends on the blood concentration of electrolytes, acid-base balance, fluid balance and overall clinical condition of the patient. The volume of replacement~~substitution~~ solution and/or dialysate to be administered will also depend on the desired intensity (dose) of the treatment ~~performed and on the amount of~~. The solution, ~~which has to~~ should be ~~replaced in order to achieve the target fluid balance. The~~ prescribed and administration (dose, infusion rate, and cumulative volume ~~is therefore at the discretion of the responsible~~) should be established only by a physician~~.~~ experienced in critical care medicine and CRRT (Continuous Renal Replacement Therapy).

Commonly used flow rates for the substitution solution in haemofiltration and haemodiafiltration are:
~~Adults~~Adult: 500 ~~-1500~~ 3000 ~~ml~~mL/hour
~~Children: 15-20 ml/kg/hour~~

Commonly used flow rates for the dialysis solution (dialysate) in continuous haemodialysis are:
~~Adults:~~ Adult: 500 - 2500 mL/hour

Children: 15 -20 ml/kg/hour

Commonly used flow rates in adults are approximately 2000 to 2500 ml/~~hour~~h which correspond to a daily fluid volume of approximately 48 to 60 L.

Special population:
Elderly population
Evidence from clinical studies and experience suggests that use in the elderly population is not associated with differences in safety or effectiveness.

Paediatric population:
The range of flow rates for the substitution solution in haemofiltration and haemodiafiltration and for the dialysis solution (dialysate) in continuous haemodialysis are:
Children (from neonates to adolescents to 18 years): 1000 to 2000 mL/h/1.73 m^2.
Flow rates up to 4,000 mL/h/1.73 m^2 may be needed, especially in younger children (≤10 kg). The absolute flow rate (in mL/h) in the paediatric population should generally not exceed the maximum adult flow rate.

Method of administration:

For use with Hemodialysis machines.

HEMOSOL B0, when used as a substitution solution is administered into the extracorporeal circuit before (pre-dilution) or after the haemofilter or haemodiafilter (post-dilution).

For instructions on reconstitution of the medicinal product before administration, see section 6.6.

החמרות בעלון לרופא:

4.4 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.

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.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions with other medications due to electrolyte and/or acid-base imbalances can be avoided by correct dosage of the solution for haemodialysis/haemofiltration and precise monitoring.

However, the following interactions are conceivable:

- The risk of digitalis-induced cardiac arrhythmia is increased during hypokalaemia;
- Vitamin D and vitamin D analogues, as well as medicinal products containing calcium (e.g. calcium chloride or calcium gluconate used for maintenance of calcium homeostasis, in CRRT patients receiving citrate anticoagulation and calcium carbonate as phosphate binder) can increase the risk of hypercalcaemia;
- Additional sodium hydrogen carbonate (or other buffer source) contained in the CRRT fluids or in other fluids administered during therapy may increase the risk of metabolic alkalosis;
- When citrate is used as an anticoagulant, it contributes to the overall buffer load and can reduce plasma calcium levels.

4.8 Undesirable effects

System Organ Class	Preferred Term	Frequency
Metabolism and nutrition disorders	Electrolyte imbalances, e.g.: hypophosphataemia, hypokalaemia	Not known
	Acid-base balance disorders	Not known
	Fluid imbalance	Not known
Vascular disorders	Hypotension	Not known
Gastrointestinal disorders	Nausea	Not known
	Vomiting	Not known
Musculoskeletal and connective tissue disorders	Muscle spasms	Not known

4.9 Overdose

If hypervolaemia or hypovolaemia occur, this should be corrected immediately.
If electrolyte imbalance and acid-base balance abnormalities (e.g., metabolic alkalosis, hypophosphataemia, hypokalaemia, etc.) occur, stop administration promptly. There is no specific antidote for overdose. The risk can be minimized by close monitoring and adequate supplementation during treatment (see section 4.4).

6.6 Special precautions for disposal

Mix the solution thoroughly when additives have been introduced. The introduction and mixing of additives must always be performed prior to connecting the solution bag to the extracorporeal circuit.

העלון המאושר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום, בקסטר אספקת שירותי בריאות בע"מ, טלפון: 054-5656441.

בברכה,

בקסטר אספקת שירותי בריאות בע"מ