Baxter

PrismOcal B22

CRRT SOLUTION

# PrismOcal B22

Bicarbonate-buffered dialysis solution for CRRT
Powered By **PrisMax** and **Prismaflex**

# PrismOcal B22

## Dialysis Solution for Continuous Renal Replacement Therapy (CRRT)

For safe and proper use of product mentioned herein, please refer to the Instructions for Use.

### INTENDED PURPOSE

The solution is used as dialysis solution in continuous haemodialysis or continuous haemodiafiltration.

### CAUTION

The instructions for use must be strictly followed.

As the solution is calcium-free, special attention should be given to calcium blood levels. Phosphate substitution and calcium supplement might be necessary. Phosphate up to 1.2 mmol/L may be added to the **PrismOcal B22**. If potassium phosphate is added, the total potassium concentration should not exceed 4 mEq/L (4 mmol/L).

The inorganic phosphate concentration should be measured regularly. Inorganic phosphate must be substituted in cases of hypophosphataemia.

The rate at which **PrismOcal B22** is administered depends on the blood concentration of electrolytes, acid–base balance, fluid balance and overall clinical condition of the patient. The volume of dialysate to be administered will also depend on the desired intensity (dose) of the treatment. The solution should be prescribed and administration (dose, infusion rate, and cumulative volume) should be established only by a physician experienced in critical care medicine and CRRT.

During treatment, haemodynamic status, fluid balance, electrolyte and acid-base balance should be closely monitored throughout the procedure.

Only for use with machines intended for continuous renal replacement therapy.

### WARNINGS

Not for direct intravenous infusion.

Not to be used as substitution fluid.

The product is for single use only. It contains sterile solutions and reuse of the product may lead to infection.

Do not use the product after the expiry date printed on the box label and on the back of the bag.

**PrismOcal B22** should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Use only if the overwrap and solution bag are undamaged. Use only if the solution is clear and the seals are intact.

From a chemical point of view, once opened (i.e. after removal of the overwrap), the reconstituted solution should be used immediately.

If heating of the solution to body temperature (+37°C) is necessary, the procedure must be carefully controlled, verifying that the solution is clear and without particles. Warming of **PrismOcal B22** prior to use should be done before reconstitution with dry heat only (e.g., heating pad, warming plate). Solutions should not be heated in water or in a microwave oven due to the potential for patient injury or discomfort.

Any unused solution or empty container must be discarded per local regulations.

Stability of the product after removal of the overwrap and subsequent reconstitution is 24 hours including the duration of treatment. Other storage times and conditions prior to use are the responsibility of the user.

Store between +4°C and +30°C.

The product should be used with caution in patients with hyperkalaemia (high potassium level). The serum potassium concentration must be monitored before and during hemodiafiltration and/or hemodialysis.

**PrismOcal B22** is a potassium-containing solution. If hyperkalemia occurs after treatment is initiated, additional sources of potassium influencing blood concentrations should be assessed. If hyperkalemia does not resolve, stop the infusion promptly. If hyperkalemia develops when **PrismOcal B22** is used as a dialysate, administration of a potassium-free dialysate may be necessary to increase the rate of potassium removal.

Because **PrismOcal B22** contains glucose and lactate (which is metabolized to glucose), hyperglycemia may develop. Blood glucose levels should be monitored regularly. If hyperglycemia develops, administration of glucose-free replacement solution/dialysate may be necessary. Other corrective measures may be needed to maintain desired glycemic control.

**PrismOcal B22** contains hydrogen carbonate (bicarbonate), and lactate (a bicarbonate precursor) which can influence the patient's acid–base balance. If metabolic alkalosis develops or worsens during therapy with **PrismOcal B22**, the administration rate may need to be decreased, or the administration stopped.

Solutions containing glucose should be used with caution in patients with known allergy to corn or corn products.

The administration must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Electrolyte imbalance and acid–base balance abnormalities (e.g., metabolic alkalosis, hypophosphatemia, hypokalemia, etc.) may occur in the event of an overdose. Stop administration promptly. There is no specific antidote for overdose. The risk can be minimized by close monitoring during treatment.

### DESCRIPTION

The product is a two-compartment polyolefin bag containing sterile solutions that are non-pyrogenic. The final reconstituted solution is obtained after opening the peel seal and mixing the contents of the two compartments.

### SPECIFICATION

**Composition of the ready-to-use solution**

The product in the small (A) and the large (B) compartments are mixed to give one reconstituted solution whose composition is:

| | | mmol/l |
|---|---|---|
| Magnesium | $Mg^{2+}$ | 0.75 |
| Sodium | $Na^{+}$ | 140 |
| Potassium | $K^{+}$ | 4 |
| Lactate | $C_3H_5O_3^{-}$ | 3 |
| Glucose | $C_6H_{12}O_6$ | 6.1 |
| Bicarbonate | $HCO_3^{-}$ | 22 |
| Chloride | $Cl^{-}$ | 120.5 |

Theoretical osmolarity: 296.4 mOsm/l

### INDICATIONS

The product is used to treat patients suffering from acute renal failure or intoxication with dialyzable substances. The product is particularly indicated for patients with high blood levels of calcium (hypercalcaemia).

### CONTRAINDICATIONS

**PrismOcal B22** is contraindicated in patients with:

- Known hypersensitivity to the product
- Hypocalcaemia

### ADVERSE REACTIONS

When continuous haemodialysis is performed correctly, side effects are uncommon. Some side effects may occur, especially when too much fluid is removed from the body, including nausea, vomiting, muscle cramps and low blood pressure (hypotension). Other adverse reactions reported with similar products include electrolyte imbalance, fluid imbalance and acid-base balance disorders.

### SERIOUS ADVERSE EVENT REPORTING

For a user and/or patient if, during the use of this device, or as a result of its use, a serious incident has occurred, please report this incident to the manufacturer, and/or its authorized representative, and to the competent authority of the Member State in which the user and/or the patient is established.

### INTERACTION WITH OTHER MEDICINES

The blood concentration of dialysable drugs may be reduced during the treatment due to their removal by the extracorporeal filter. Corresponding corrective therapy should be instituted if necessary to establish the desired blood concentrations for drugs removed during treatment. The use of the solution may result in alteration of the patient's plasma electrolyte levels. The physician must carefully consider that medicines being used by the patient may be affected by this alteration.

Additional sodium bicarbonate (or 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.

Vitamin D and other 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) can increase the risk of hypercalcemia.

### PACKAGING

2 bags of 5000 ml per carton

### MANUFACTURER

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