Vantive

Prismocitrate 18/0

CRRT SOLUTION

PRISMOCITRATE 18/0

Sterile solution for regional citrate anticoagulation
in continuous renal replacement therapy
Powered By **PrisMax** and **Prismaflex**

PRISMOCITRATE 18/0

Ready-to-Use Sterile Anticoagulant Solution

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

INTENDED PURPOSE

Prismocitrate solution is intended for regional citrate anticoagulation in the extracorporeal circuit during continuous renal replacement therapy (CRRT).

CAUTIONS

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

Use only if the solution is clear and free from particles.

Store between +4°C and +30°C.

Continuous renal replacement therapy results in sodium removal proportional to plasma water sodium content. To avoid a drop in the blood sodium level in the patient (hyponatraemia) sodium losses must be balanced as part of overall fluid and electrolyte management. Administration of both CRRT related dialysis fluids and those outside of the CRRT prescription require careful assessment.

Prismocitrate may be warmed to 37°C. Warming of the product prior to use should be done with dry heat only. Solution should not be heated in water or in a microwave oven.

There are no adequate data from the use of **Prismocitrate** in pregnant or lactating women.

Physicians should carefully consider the potential risks and benefits for each specific patient before administration.

POSOLOGY

Prismocitrate is to be used in hospitals and administered by medical professionals only. The volume used, and therefore the dose of this medicine, will depend on your condition.

WARNINGS

Not for direct intravenous infusion. The solution must be used in pre-dilution mode only with a dialysis machine intended for continuous renal replacement therapy, provided that the dialysis machine is suitable for citrate anticoagulation.

Use only if the overwrap and solution bag are undamaged. To avoid microbiological contamination, the solution should be used immediately after opening the overwrap.

The product should be inspected visually for particulate matter and discolouration prior to administration, whenever solution and container permit.

The patient's haemodynamic status, as well as the fluid, electrolyte and acid-base balances, must be closely monitored throughout treatment. Infusion of electrolytes may be needed to supplement any loss.

Considering the composition of this solution, other solutions used in the treatment must have appropriate hydrogen carbonate concentration.

The **Prismocitrate** solution is calcium- and magnesium-free and could cause severe hypoglycaemia and/or hypomagnesaemia.

The **Prismocitrate** solution could produce a severe disruption of the acid-base balance (alkalosis). If metabolic alkalosis occurs, decrease the citrate dose, and/or increase the dialysate flow rate or change the composition of the CRRT solution.

Depending on the composition of other solutions used during the treatment, a separate infusion of sufficient magnesium and/or sodium might be necessary.

Dose reduction may be needed in patients with mild to moderate hepatic impairment; more frequent monitoring of citrate accumulation is advised.

Plasma levels of sodium, magnesium, potassium, and phosphate should be monitored regularly and should be supplemented as needed.

A separate infusion of calcium is always required. Adjust or stop calcium infusion according to physician's prescription when **Prismocitrate** anticoagulation is stopped. Blood calcium levels should be monitored regularly in patients with metabolic alkalosis since this condition may potentiate hypoglycaemia.

Metabolic acidosis may occur if metabolic clearance of citrate by the liver or skeletal muscle is impaired. Metabolism of citrate (to bicarbonate) may be impaired in patients with hepatic impairment, resulting in accumulation of citrate. If citrate accumulation develops and/or metabolic acidosis develops or worsens during therapy with **Prismocitrate**, the infusion rate may need to be decreased or its administration stopped. If the product is administered to patients with mild to moderate hepatic impairment, frequent monitoring of pH, electrolytes, total-to-ionised calcium ratio, and systemic ionised calcium is important to avoid electrolyte and/or acid-base imbalance.

Prismocitrate is hypoosmolar/hypotonic relative to standard CRRT replacement fluids and should be used with caution in patients with traumatic brain injury, cerebral oedema, or increased intracranial pressure.

The instructions for use must be strictly followed. Incorrect use of the access port or other restrictions to fluid flow might lead to incorrect patient weight loss and may result in machine alarms. Continuing treatment without resolving the originating cause may result in patient injury or death.

The **Prismocitrate** product is for single use only. It contains sterile solution, and reuse of the product may lead to infection. Use of a contaminated solution may cause sepsis and shock. Any unused solution must be discarded per local regulations.

DESCRIPTION

The **Prismocitrate** product is a ready-to-use sterile anticoagulant solution in one compartment bag of polyolefin material. The solution is clear, colourless and non-pyrogenic.

SPECIFICATION

Composition of the ready-to-use solution

		mmol/l
Citrate	$C_6H_5O_7^{3-}$	18
Sodium	Na^+	140
Chloride	Cl^-	86

Theoretical osmolarity: 244 mOsm/l pH 7.0-8.0

INDICATIONS

The **Prismocitrate** solution is indicated for patients treated with continuous renal replacement therapy in citrate anticoagulation mode and particularly for patients with high risk of bleeding or suffering from heparin induced thrombocytopenia.

CONTRAINDICATIONS

Prismocitrate is contraindicated in patients with known hypersensitivity to the product, severe liver failure and shock with muscle hypoperfusion.

ADVERSE REACTIONS

The product contains citrate, which contributes to the overall buffer load. It does not contain any calcium, magnesium, glucose or potassium. Use of the solution could produce a severe disruption of the acid-base balance (alkalosis) and/or a severe drop in the blood calcium level (hypoglycaemia) and/or the blood magnesium level (hypomagnesaemia) and/or the blood of dextrose level (hypoglycaemia).

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. Metabolic alkalosis may occur if the net citrate administration rate exceeds that which is necessary to maintain acid-base balance. Electrolyte imbalance and acid-base balance abnormalities (e.g., hypoglycaemia, metabolic alkalosis, etc.) may occur in the event of an overdose. Stop administration promptly.

Careful calcium supplementation can reverse the effects of an overdose. The risk can be minimised by close monitoring during treatment. In patients with impaired citrate metabolism (e.g., liver failure, shock, etc.), product overdose may be manifested as citrate accumulation, metabolic acidosis, systemic total hypercalcaemia and ionised hypoglycaemia along with increased total calcium/ionised calcium ratio.

Other adverse reactions reported with similar products include hypotension, acid-base balance disorders, electrolyte imbalance and fluid imbalance.

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 authorised representative, and to the competent authority of the Member State in which the user and/or the patient is established.

INTERACTION WITH MEDICINES

Medicinal products containing calcium, as well as vitamin D and vitamin D analogues, as well as medicinal products containing calcium can increase the risk of hypercalcaemia, and can result in a reduced anticoagulation effect. The blood concentration of filterable/dialysable drugs may be reduced during 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.

PACKAGING

Each box contains 2 bags of 5000 ml solution.

MANUFACTURER

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