Vantive

Phoxilium

CRRT SOLUTION

PHOXILIUM
1.2 mmol/l Phosphate

Bicarbonate-buffered solution for haemodialysis and haemofiltration

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

PHOXILIUM 1.2 mmol/l Phosphate
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

Phoxilium 1.2 mmol/l phosphate solution for haemodialysis/haemofiltration

QUALITATIVE AND QUANTITATIVE COMPOSITION

Phoxilium is presented in a two-compartment bag. The final reconstituted solution is obtained after breaking the peel seal and mixing both solutions.

BEFORE RECONSTITUTION

1000 ml of solution in the small compartment (A) contains:	
Calcium chloride, $2H_2O$	3.68 g
Magnesium chloride, $6H_2O$	2.44 g
1000 ml of solution in the large compartment (B) contains:	
Sodium chloride	6.44 g
Sodium hydrogen carbonate	2.92 g
Potassium chloride	0.314 g
Disodium phosphate, $2H_2O$	0.225 g

AFTER RECONSTITUTION

1000 ml of the reconstituted solution contains:

		mmol/l	mEq/l
Calcium	Ca^{2+}	1.25	2.50
Magnesium	Mg^{2+}	0.600	1.20
Sodium	Na^{+}	140.0	140.0
Chloride	Cl^{-}	115.9	115.9
Hydrogen phosphate	HPO_4^{2-}	1.20	2.40
Hydrogen carbonate	HCO_3^{-}	30.0	30.0
Potassium	K^{+}	4.00	4.00

Each 1000 ml of the final reconstituted solution corresponds to 50 ml of solution A and 950 ml of solution B.

Theoretical osmolarity: 293 mOsm/l

pH of the reconstituted solution: 7.0-8.5

For the full list of excipients, see the full SPC.

CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

Phoxilium is used for CRRT (continuous renal replacement therapy) in critically ill patients with ARF (acute renal failure) when pH and kalaemia have been restored to normal and when the patients need phosphate supplementation for loss of phosphate in the ultrafiltrate or to the dialysate during CRRT.

Phoxilium may also be used in cases of drug poisoning or intoxications when the poisons are dialysable or pass through the membrane.

Phoxilium is indicated for use in patients with normal kalaemia and normal or hypophosphataemia.

CONTRAINDICATIONS

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 of the full SPC.

Solution dependent contraindications

> Hyperkalaemia
> Metabolic alkalosis
> Hyperphosphataemia

Haemofiltration/- dialysis dependent contraindications

> Renal failure with pronounced hypercatabolism, if the uraemic symptoms cannot be corrected with haemofiltration or haemodiafiltration
> Insufficient arterial pressure in the vascular access
> Systemic anticoagulation if there is a high risk of haemorrhage

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The solution shall be used only by, or under the direction of, a physician competent in CRRT treatments using haemofiltration, haemodiafiltration and haemodialysis.

Warnings:

Phoxilium should not be used in patients with hyperkalaemia (see section Contraindications). The serum potassium concentration must be monitored before and during haemofiltration and/or haemodialysis.

Because **Phoxilium** is a potassium-containing solution, hyperkalaemia may occur transiently after treatment is initiated. Decrease the infusion rate and confirm that the desired potassium concentration is achieved. If hyperkalaemia does not resolve, stop administration promptly.

If hyperkalaemia develops when **Phoxilium** is used as a dialysate, administration of a potassium-free dialysate may be necessary to increase the rate of potassium removal.

Because **Phoxilium** is a phosphate-containing solution, hyperphosphataemia may occur transiently after treatment is initiated. Decrease the infusion rate and confirm that the desired phosphate concentration is achieved. If hyperphosphataemia does not resolve, stop administration promptly (see section Contraindications).

Electrolyte and blood acid/base parameters should be monitored regularly in patients treated with **Phoxilium**. **Phoxilium** contains hydrogen phosphate, a weak acid that can influence the patient's acid/base balance. If metabolic acidosis develops or worsens during therapy with **Phoxilium**, the infusion rate may need to be decreased or its administration stopped.

Because **Phoxilium** contains no glucose, administration may lead to hypoglycaemia. Blood glucose levels should be monitored regularly in diabetic patients (including careful consideration of patients receiving insulin or other glucose lowering medications), but also considered in non-diabetic patients, e.g. risk for silent hypoglycaemia during the procedure. If hypoglycaemia develops, use of a glucose-containing solution should be considered. Other corrective measures may be necessary to maintain desired glycaemic control.

The Instructions for Use (see section 6.6 of the full SPC) must be strictly followed. The solutions in the two compartments must be mixed before use. Use of a contaminated solution may cause sepsis or shock.

Do not administer the solution unless it is clear. Aseptic technique must be used during connection / disconnection of the line sets to the **Phoxilium** container.

Use only with an appropriate extracorporal renal replacement equipment.

Special precautions for use:

Phoxilium 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. **Phoxilium** 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.

Haemodynamic status, fluid balance, electrolyte and acid-base balance shall be closely monitored throughout the procedure including all fluid inputs and outputs, even those not directly related to CRRT.

In case of hypervolaemia, the net ultrafiltration rate prescribed for the CRRT device can be increased and/or the rate of administration of solutions other than replacement fluid and/or dialysate can be reduced. In case of hypovolaemia, the net ultrafiltration rate prescribed for the CRRT device can be reduced and/or the rate of administration of solutions other than replacement fluid and/or dialysate can be increased.

FERTILITY, PREGNANCY AND LACTATION

Fertility: No effects on fertility are anticipated, since calcium, sodium, potassium, magnesium, chloride, hydrogen phosphate and hydrogen carbonate are normal constituents of the body.

Pregnancy and lactation: There are no documented clinical data on the use of **Phoxilium** during pregnancy and lactation. **Phoxilium** should only be administered to pregnant and lactating women if clearly needed.

UNDESIRABLE EFFECTS

Undesirable effects can result from the solution used or the treatment.

Bicarbonate-buffered haemofiltration and haemodialysis solutions are generally well tolerated.

The following undesirable effects have been reported from post-marketing experience.

Undesirable effects related to the solution:

> Undesirable effects are (frequency not known): electrolyte imbalances (e.g., hyperphosphataemia), fluid imbalance (e.g., hypervolaemia, hypovolaemia), acid-base balance disorders (e.g., metabolic acidosis, metabolic alkalosis).

Undesirable effects related to the dialysis treatment:

> Undesirable effects are (frequency not known): hypotension, nausea, vomiting, muscle cramps.

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, overdose, pharmacological properties and pharmaceutical particulars, please refer to the full SPC.

Medicinal product subject to medical prescription.

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Australia
Vantive Pty Ltd
A.B.N. 91 625 652 280
1 Baxter Drive, Old Toongabbie
NSW 2146, Australia
T: 1800 920 133

New Zealand
Vantive Limited
G.S.T Reg No. 140-208-558
33 Vestey Drive,
Mt Wellington, Auckland NZ
T: 0800 436 770

ANZ-AT12-240001

pro.vantive.com.au