Prescribing Information (UK)
(Please refer to the full Summary of Product Characteristics before using)

multiBic potassium free Solution for Haemofiltration, MA No: PL 13689/0014
multiBic 2 mmol/l potassium Solution for Haemofiltration MA No: PL 13689/0015
multiBic 3 mmol/l potassium Solution for Haemofiltration MA No: PL 13689/0016
multiBic 4 mmol/l potassium Solution for Haemofiltration MA No: PL 13689/0017

Composition:
1 litre of the neutral ready-to-use solution contains:

Active substances in g/l	multiBic Pottasium free	multiBic 2mmol potassium	multiBic 3mmol potassium	multiBic 4mmol potassium
Sodium chloride	6.136 g	6.136 g	6.136 g	6.136 g
Potassium chloride	0g	0.1491 g	0.2237 g	0.2982 g
Sodium hydrogen carbonate	2.940 g	2.940 g	2.940 g	2.940 g
Calcium chloride dihydrate	0.2205 g	0.2205 g	0.2205 g	0.2205 g
Magnesium chloride hexahydrate	0.1017 g	0.1017 g	0.1017 g	0.1017 g
Glucose, anhydrous (as glucose monohydrate)	1.000 g (1.100 g)	1.000 g (1.100 g)	1.000 g (1.100 g)	1.000 g (1.100 g)

1 litre of the neutral ready-to-use solution contains:

Active substances in mmol/l	multiBic Pottasium free	multiBic 2mmol potassium	multiBic 3mmol potassium	multiBic 4mmol potassium
Na^+	140 mmol	140 mmol	140 mmol	140 mmol
K^+	0	2.0 mmol	3.0 mmol	4.0 mmol
Ca^{2+}	1.5 mmol	1.5 mmol	1.5 mmol	1.5 mmol
Mg^{2+}	0.50 mmol	0.50 mmol	0.50 mmol	0.50 mmol
Cl^-	109 mmol	111 mmol	112 mmol	113 mmol
HCO3-	35 mmol	35 mmol	35 mmol	35 mmol
Glucose	5.55 mmol	5.55 mmol	5.55 mmol	5.55 mmol
Theoretical osmolarity (mosm/l)	292 mosm/l	296 mosm/l	298 mosm/l	300 mosm/l

Presentation: Double chamber bag with 4750 ml (alkaline hydrogen carbonate solution) and 250 ml (acidic electrolyte, glucose solution) gives 5 litre of ready to use solution. **Indications:** multiBic is indicated for intravenous use as substitution solution in haemofiltration and haemodiafiltration, and as dialysis solution in haemodialysis and haemodiafiltration. For use in patients - With acute kidney injury requiring continuous renal replacement therapy: continuous haemodialysis, haemofiltration or haemodiafiltration treatments. - With chronic kidney disease in whom a transient treatment is indicated, e.g. during the stay on an intensive care unit. - When continuous renal replacement therapy is indicated as part of the treatment of intoxication with water soluble, filterable/dialyzable toxins. **Dosage and Administration:** In acute kidney injury, a continuous treatment with a dose of 2000 ml/h multiBic potassium-free/2/3/4 mmol/l potassium is appropriate in adults with a body weight of 70 kg to remove metabolic waste products depending on the metabolic status of the patient. The dose should be adapted to the body size of the patient. In patients with chronic kidney disease, unless clinically indicated otherwise, the dose of multiBic potassium-free/2/3/4 mmol/l potassium should be at least one third of the body weight per session with three sessions applied per week. Increasing the volume applied per week or distributing this weekly volume to more than 3 treatments per week can be required. A maximum dose of 75 litres per day is recommended. Paediatric population: The safety and efficacy of multiBic potassium-free/2/3/4 mmol/l potassium in children have not yet been established (see sections 4.4 and 5.1). **Contraindications**: **multiBic potassium-free/2/3 mmol/l potassium**: -Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 - Hypokalaemia - Metabolic alkalosis. **multiBic 4 mmol/l potassium:** - Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 – Hyperkalaemia- Metabolic alkalosis.
Contraindications for use of the technical procedure itself: - Inadequate blood flow from vascular access. - If there is a high risk of haemorrhage on account of systemic anticoagulation. **Warnings and Precautions:** Use only after mixing of the two solutions. multiBic potassium-free/2/3/4 mmol/l potassium should be warmed prior to use with appropriate equipment to approximately body temperature and must not be used under any circumstances below room temperature. During application of the ready-to-use solution, white calcium carbonate precipitation has been observed in the tubing lines in rare cases, particularly close to the pump unit and the heating unit warming the ready-to-use solution. Precipitations particularly can occur if the temperature of the ready-to-use solution at the inlet of the pump unit is already higher than 30°C. Therefore, the ready-to-use solution in the tubing lines must be closely visually inspected every 30 min during continuous renal replacement therapy in order to ensure, that the solution in the tubing system is clear and free from precipitate. Precipitations may occur also with substantial delay after start of treatment. If precipitate is observed, the ready-to-use solution and the tubing lines used for continuous renal replacement therapy must be replaced immediately and the patient carefully monitored. The serum potassium concentration must be checked regularly before and during continuous renal replacement therapy. The potassium status of the patient and its trend during the treatment must be considered: In case of hypokalaemia supplementation of potassium and / or changing to a solution for haemodialysis/ haemofiltration with higher potassium concentration may be required. In case of hyperkalaemia an increase in the applied dose and / or change to a solution for haemodialysis/haemofiltration with a lower potassium concentration may be indicated as well as usual measures of intensive care medicine. The serum sodium concentration must be checked regularly before and during use of this solution for haemodialysis/ haemofiltration to control risks related to hypo/hypernatraemia. The solution for haemodialysis/haemofiltration may be diluted with an adequate amount of water for injections or concentrated sodium chloride solution may be added if required. The speed of desired normalisation must then be carefully planned to avoid adverse reactions due to rapid changes in serum sodium concentration. In addition, the following parameters must be monitored before and during continuous renal replacement therapy: Serum calcium, serum magnesium, serum phosphate, serum glucose, acid-base status, levels of urea and creatinine, body weight and fluid balance (for the early recognition of hyper- and dehydration). **Interactions:** No interaction studies have been performed. The following interactions are conceivable: - Toxic effects of digitalis may be masked by hyperkalaemia, hypermagnesaemia and hypocalcaemia. The correction of these electrolytes by continuous renal replacement therapy may precipitate signs and symptoms of digitalis toxicity, e.g. cardiac arrhythmia. - Electrolyte substitutions, parenteral nutrition and other infusions usually given in intensive care medicine interact with the serum composition and the fluid status of the patient. This must be considered during application of continuous renal replacement therapy. - Continuous renal replacement therapy may reduce the blood concentration of drugs, especially of drugs with a low protein binding capacity, with a small distribution volume, with a molecular weight below the cut-off of the haemofilter and of medicinal products adsorbed to the haemofilter. An appropriate revision of the dose of such medicinal products may be required. **Fertility, Pregnancy and Lactation**: **Pregnancy** - There are no or limited amount of data from the use of multiBic potassium-free/2/3/4 mmol/l potassium in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). multiBic potassium-free/2/3/4 mmol/l potassium should not be used during pregnancy unless the clinical condition of the woman requires continuous renal replacement therapy**. Breastfeeding** - There is insufficient information on the excretion of multiBic potassium-free/2/3/4 mmol/l potassium active substances/metabolites in human milk. Breastfeeding is not recommended during treatment with multiBic potassium-free/2/3/4 mmol/l potassium. **Fertility**- No data available. **Effects on ability to drive and use machines:** Not relevant. **Undesirable effects:** Adverse reactions may result from the treatment mode itself or may be induced by this medicinal product: Gastrointestinal disorders - nausea, vomiting. Vascular disorders - hypertension, hypotension. Musculoskeletal and connective tissue disorders - muscle cramps. The following adverse reaction can be anticipated for the treatment mode: Metabolism and nutrition disorders - hyper- or hypohydration, electrolyte disturbances (e.g., hypokalaemia), hypophosphataemia, hyperglycaemia, and metabolic alkalosis. **Pack size and price:** 5000ml bag £15. **Legal category:** POM**. MA Holder:** Fresenius Medical Care Deutschland GmbH Else-Kröner-Straße 1, 61352 Bad Homburg v.d.H., Germany. Further information available from Fresenius Medical Care (UK) Ltd (Sale and supply) Nunn Brook Road, Huthwaite, Sutton-in-Ashfield, NG17 2HU
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Fresenius Medical Care Vigilance team on 01623 445 100

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