

Prescribing Information

balance 1.5% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 2.3% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 4.25% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 1.5% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, balance 2.3% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, balance 4.25% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis. These solutions are delivered in a double chamber bag. One chamber contains the alkaline lactate solution, the other chamber contains the acidic glucose-based electrolyte solution. Mixing of both solutions by opening the middle seam between the two chambers results in the neutral ready-to-use solution. **Composition: 1 litre of the neutral ready-to-use solution contains:** *balance 1.5% glucose, 1.75 mmol/l calcium:* sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 15 g. *balance 2.3% glucose, 1.75 mmol/l calcium:* sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 22.73 g. *balance 4.25% glucose, 1.75 mmol/l calcium:* sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 42.5 g. *balance 1.5% glucose, 1.25 mmol/l calcium:* sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.1838 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 15 g. *balance 2.3% glucose, 1.25 mmol/l calcium:* sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.1838 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 22.73 g. *balance 4.25% glucose, 1.25 mmol/l calcium:* sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.1838 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 42.5 g. **Excipients:** Water for injections, hydrochloric acid, sodium hydroxide, sodium hydrogen carbonate. **Indications:** End-stage (decompensated) chronic renal failure of any origin treated with peritoneal dialysis. **Contraindications: Solution related:** Solutions with 1.5%/2.3%/4.25% glucose, 1.75 mmol/l calcium: Severe hypokalaemia and severe hypercalcaemia. Solutions with 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium: Severe hypokalaemia and severe hypocalcaemia. Solutions with 4.25% glucose: Additionally hypovolaemia and arterial hypotension. **Treatment related:** Recent abdominal surgery or injury, burns, hernia, inflammatory abdominal skin reaction (dermatitis), inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis), peritonitis, non-healing weeping wounds (abdominal fistulae), intra-abdominal tumours, intestinal obstruction (ileus), lung diseases (especially pneumonia), metabolic disorders (lactic acidosis), generalised blood poisoning (sepsis), extreme weight loss (cachexia), particularly when adequate nutrition is impossible, in cases of accumulation of uraemic toxins in the blood (uraemia) the elimination of which can not be managed by peritoneal dialysis, very high levels of fat in the blood (hyperlipidaemia). **Undesirable effects: Infections:** Peritonitis (very common); skin exit site and tunnel infections (very common); in very rare cases sepsis. Disorders of the hormone balance for solutions containing 1.25 mmol/l calcium. Overactivity of the parathyroid gland with potential disorders of the bone metabolism. Metabolism and nutrition disorders. Increased blood sugar and fat levels; increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution. **Cardiac and vascular disorders:** Frequent pulse; decreased or increased blood pressure. **Respiratory disorders:** Shortness of breath due to elevation of the diaphragm, shoulder pain. **Gastrointestinal disorders:** Diarrhoea; constipation; hernia (very common); abdominal distension and sensation of fullness. **Renal disorders:** Electrolyte disturbances, e.g. decreased potassium levels (very common), increased calcium levels in combination with an increased calcium uptake, e.g. by the administration of calcium containing phosphate binders or decreased calcium levels for solutions containing 1.25 mmol/l calcium. **General disorders and administration/catheter site conditions:** General malaise; redness, swellings, exudations, crusts and pain at the catheter exit site; dizziness; oedema; disturbances in hydration indicated either by a rapid decrease (dehydration) or increase (overhydration) in body weight. Severe dehydration might occur when using solutions of higher glucose concentration. **Peritoneal dialysis procedure related disorders:** Cloudy effluent; in- and outflow disturbances of the dialysis solution. **Warnings and Precautions:** Do not use unless solution is clear and container undamaged. For single use only. Any unused portion of the solution is to be discarded. Do not use before mixing both solutions. The ready-to-use solution must be used within 24 hours after mixing. Do not store below 4°C. **Date:** December 2010. **Fresenius Medical Care Deutschland GmbH**, 61346 Bad Homburg v.d.H., Germany.

bicaVera® 1.5% Glucose, Solution for peritoneal dialysis, bicaVera® 2.3% Glucose, Solution for peritoneal dialysis, bicaVera® 4.25% Glucose, Solution for peritoneal dialysis. These solutions are delivered in a double chamber bag. One chamber contains the alkaline hydrogen carbonate solution, the other chamber contains the acidic glucose-based electrolyte solution. Mixing of both solutions by opening the median seam between the two chambers results in the ready-to-use solution. **Composition: 1 litre of the ready-to-use solution contains:** *bicaVera® 1.5% Glucose:* sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, anhydrous glucose (as glucose monohydrate) 15 g. *bicaVera® 2.3% Glucose:* sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, anhydrous glucose (as glucose monohydrate) 22.73 g. *bicaVera® 4.25% Glucose:* sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, anhydrous glucose (as glucose monohydrate) 42.5 g. **Excipients:** Hydrochloric acid, sodium hydroxide, carbon dioxide, water for injections. **Indications:** End-stage (decompensated) chronic renal failure of any origin treated with peritoneal dialysis. **Contraindications: Solution specific:** *bicaVera® 1.5% Glucose:* severe hypokalaemia, severe hypercalcaemia. *bicaVera® 2.3% Glucose, bicaVera® 4.25% Glucose:* severe hypokalaemia, severe hypercalcaemia, hypovolaemia, hypotension. **For peritoneal dialysis in general:** Recent abdominal surgery or injury, a history of abdominal operations with fibrous adhesions, severe abdominal burns, bowel perforation; extensive inflammatory conditions of the abdominal skin (dermatitis); inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis); localized peritonitis; internal or external abdominal fistula; umbilical, inguinal or other abdominal hernia; intra-abdominal tumours; ileus; pulmonary disease (especially pneumonia); sepsis; extreme hyperlipidaemia; in rare cases of uraemia, which can not be managed by peritoneal dialysis; cachexia and severe weight loss, particularly in cases in which the ingestion of adequate protein is not guaranteed; patients who are physically or mentally incapable of performing PD as instructed by the physician. **Side effects: Solution specific:** Electrolyte disturbances, e.g. hypokalaemia, hypercalcaemia in combination with an increased calcium uptake, e.g. by the administration of calcium-containing phosphate binders; disturbances in hydration. A rapid decrease in body weight, the drop in blood pressure and/or tachycardia may indicate dehydration; oedema, hypertension and possibly dyspnoea may indicate overhydration; increased blood sugar levels; hyperlipidaemia; increase in body weight. **For peritoneal dialysis in general:** Peritonitis, indicated by cloudy effluent, later abdominal pain, fever, and malaise may develop or, in very rare cases, generalised blood poisoning (sepsis); skin exit site infection or tunnel infection of the catheter indicated by redness, oedema, pain, exudations or crusts; in- and outflow disturbances of the dialysis solution, diarrhoea or obstipation, dyspnoea caused by the elevated diaphragm; hernia; abdominal dilatation and sensation of fullness; shoulder pain. **Warnings and Precautions:** Do not use unless the solution is clear and the container is undamaged. For single use only. Any unused residual solution should be discarded. Do not use before the two solutions have been mixed. The ready-to-use solution must be used within 24 hours after mixing. Do not store below 4°C. **Date:** December 2010. **Fresenius Medical Care Deutschland GmbH**, 61346 Bad Homburg v.d.H., Germany.