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

bicaVera 1.5% glucose, 1.75 mmol/l Calcium, solution for peritoneal dialysis MA No: PL 13689/0008
bicaVera 2.3% glucose, 1.75 mmol/l Calcium, solution for peritoneal dialysis MA No: PL 13689/0010
bicaVera 4.25% glucose,1.75 mmol/l Calcium, solution for peritoneal dialysis MA No: PL 13689/0009
bicaVera 1.5% glucose, 1.25 mmol/l Calcium, solution for peritoneal dialysis MA No: PL 13689/0021
bicaVera 2.3% glucose, 1.25 mmol/l Calcium, solution for peritoneal dialysis MA No: PL 13689/0022
bicaVera 4.25% glucose, 1.25 mmol/l Calcium, solution for peritoneal dialysis MA No: PL 13689/0023

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Date of preparation: August 2023
Job bag: UK-BIC-000001

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

Active substances in g/l	**BicaVera 1.5%** Glucose, 1.75mmol/l Calcium	**BicaVera 2.3%** glucose, 1.75mmol/l Calcium	**BicaVera 4.25%** glucose, 1.75mmol/l Calcium	**BicaVera 1.5%** Glucose, 1.25mmol/l Calcium	**BicaVera 2.3%** glucose, 1.25mmol/l Calcium	**BicaVera 4.25%** glucose, 1.25mmol/l Calcium
Sodium chloride	5.786	5.786	5.786	5.786	5.786	5.786
Sodium hydrogen carbonate	2.940	2.940	2.940	2.940	2.940	2.940
Calcium chloride dihydrate	0.2573	0.2573	0.2573	0.1838	0.1838	0.1838
Magnesium chloride hexahydrate	0.1017	0.1017	0.1017	0.1017	0.1017	0.1017
Glucose monohydrate (equivalent to glucose, anhydrous)	15.0	22.73	42.5	15.0	22.73	42.5

Active substances in mmol/l	**BicaVera 1.5%** Glucose, 1.75mmol/l Calcium	**BicaVera 2.3%** glucose, 1.75mmol/l Calcium	**BicaVera 4.25%** glucose, 1.75mmol/l Calcium	**BicaVera 1.5%** Glucose, 1.25mmol/l Calcium	**BicaVera 2.3%** glucose, 1.25mmol/l Calcium	**BicaVera 4.25%** glucose, 1.25mmol/l Calcium
Na^+	134.0	134.0	134.0	134.0	134.0	134.0
Ca^{2+}	1.75	1.75	1.75	1.25	1.25	1.25
Mg^{2+}	0.5	0.5	0.5	0.5	0.5	0.5
Cl^-	104.5	104.5	104.5	104.5	104.5	104.5
HCO_3	34.0	34.0	34.0	34.0	34.0	34.0
Glucose	83.25	126.1	235.9	83.25	126.1	235.9
Theoretical osmolarity (mosm/l)	358	401	511	357	399	509
pH	7.4					

Presentation: stay safe: The stay safe system is provided as a double bag system consisting of a double-chamber solution bag and a drainage bag, both with injection units, a transfer tubing system and a system connector. **sleep safe:** The sleep safe system is provided as a single bag system consisting of a double-chamber solution bag with an injection unit, a transfer tubing system and a bag connector. **Indications:** End-stage (decompensated) chronic renal failure of any origin treated with peritoneal dialysis. **Dosage and Administration:** The mode of therapy, frequency of administration, and dwell time required will be specified by the attending physician. Continuous ambulatory peritoneal dialysis (CAPD)- **Adults**: Unless otherwise advised, patients will receive an infusion of 2000 ml solution per exchange four times a day. After a dwell time between 2 and 10 hours the solution will be drained. **Children**: In children the solution volume per exchange should be prescribed according to age and body surface area (BSA). For initial prescription, the volume per exchange should be 600-800 ml/m2 BSA with 4 (sometimes 3 or 5) exchanges per day. It can be increased up to 1000-1200 ml/m2 BSA depending on tolerance, age and residual renal function. Automated peritoneal dialysis (APD): If a machine (sleep safe cycler) is used for intermittent or continuous cyclic peritoneal dialysis larger volume bags (3000 or 5000 ml) providing more than one solution exchange are used. **Adults:** Typically patients spend 8-10 hours a night cycling. Dwell volumes range from 1500 to 3000 ml and the number of cycles usually varies from 3 to 10 per night. **Children:** The volume per exchange should be 800-1000 ml/m2 BSA with 5-10 exchanges overnight. It can be increased up to 1400 ml/m2 BSA depending on tolerance, age and residual renal function. Continuous ambulatory peritoneal dialysis (CAPD) - The solution bag is first warmed up to body temperature. The heating will be performed with a heating plate. The time for heating is about 120 minutes for a 2000 ml bag at a temperature of 22º C. Automated peritoneal dialysis (APD): The connectors of the prescribed sleep safe solution bags are inserted in the free sleep safe tray ports and then automatically connected to the sleep safe tubing set by the cycler. **Contraindications:** For this specific peritoneal dialysis solution: bicaVera 1.5 % Glucose, 1.75 mmol/l Calcium must not be used in patients with severe hypokalaemia and severe hypercalcaemia. bicaVera 2.3 % Glucose, 1.75 mmol/l Calcium and bicaVera 4.25 % Glucose, 1.75 mmol/l Calcium must not be used in patients with severe hypokalaemia, severe hypercalcaemia, hypovolaemia and hypotension. Similarly, bicaVera 1.5 % Glucose, 1.25 mmol/l Calcium must not be used in patients with severe hypokalaemia and severe hypocalcaemia. bicaVera 2.3 % Glucose, 1.25 mmol/l Calcium and bicaVera 4.25 % Glucose, 1.25 mmol/l Calcium must not be used in patients with severe hypokalaemia, severe hypocalcaemia, hypovolaemia and hypotension. For peritoneal dialysis in general: Peritoneal dialysis should not be commenced in case of - 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. **Warnings and Precautions:** Encapsulating peritoneal sclerosis is considered to be a known, rare complication of peritoneal dialysis therapy which can infrequently lead to fatal outcome. bicaVera may only be administered after careful benefit-risk assessment in: patients with loss of electrolytes due to vomiting and/or diarrhoea. Patients with hypocalcaemia: It may be necessary to use a peritoneal dialysis solution with a higher calcium concentration either temporarily or permanently, in case an adequate enteral supply of calcium, by calcium-containing phosphate binders and/or vitamin D, is not possible. Patients with hyperparathyroidism: The administration of calcium-containing phosphate binders and/or vitamin D may be considered to ensure adequate enteral calcium supply.

Patients receiving digitalis therapy: Regular monitoring of the serum potassium level is mandatory. Severe hypokalaemia may necessitate the use of a potassium-containing dialysis solution besides dietary counselling. Patients with large polycystic kidneys. The monitoring of the following parameters is recommended: body weight for the early recognition of over and dehydration, serum sodium, potassium, calcium, magnesium, phosphate, acid base status and blood proteins, serum creatinine and urea, parathormone and other indicators of bone metabolism, blood sugar, residual renal function in order to adapt the peritoneal dialysis. Elderly patients: The increased incidence of hernia should be considered in elderly patients prior to the start of peritoneal dialysis.). **Interactions**: For solutions containing 1.75mmol/LCalcium. The use of this peritoneal dialysis solution can lead to a loss of efficacy of other medicinal products if these are dialysable through the peritoneal membrane. A distinct reduction of the serum potassium level can increase the frequency of digitalis-associated adverse reactions. Potassium levels must be monitored particularly closely during concurrent digitalis therapy. The concomitant administration of calcium-containing drugs as well as vitamin D may cause hypercalcaemia. The use of diuretic agents may help maintain residual diuresis, but may also result in water and electrolyte imbalances. In diabetic patients the daily dose of blood sugar reducing medication must be adjusted to the increased glucose load. For solutions containing 1.25mmol/L Calcium: The use of this peritoneal dialysis solution can lead to a loss of efficacy of other medicinal products if these are dialysable through the peritoneal membrane. A dose adjustment might become necessary. A distinct reduction of the serum potassium level can increase the frequency of digitalis-associated adverse reactions. Potassium levels must be monitored particularly closely during concurrent digitalis therapy. Special attention and monitoring is required in the case of secondary hyperparathyroidism. The therapy with calcium-containing phosphate binders and/or vitamin D may be required. The use of diuretic agents may help maintain residual diuresis, but may also result in water and electrolyte imbalances. In diabetic patients the daily dose of blood sugar reducing medication must be adjusted to the increased glucose load. **Fertility, Pregnancy and Lactation:** Fertility - No data available. Pregnancy - There are no clinical data available from use of bicaVera solutions in pregnant women. Animal studies are insufficient with respect to reproductive and developmental toxicity (see section 5.3). bicaVera solution should only be used during pregnancy when the benefit to the mother clearly outweighs the potential risks to the fetus (see section 4.4). Lactation - It is not known whether bicaVera solution ingredients are excreted in human milk. bicaVera solution should only be used in lactating women, when the benefit to the mother clearly outweighs the potential risks to the infant. Effects on ability to drive and use machines: bicaVera has no or negligible influence on the ability to drive and to use machines. **Undesirable effects:** Secondary hyperparathyroidism with potential disturbances of the bone metabolism (not known). Common: Increased blood sugar levels, Hyperlipidaemia, Increase in body weight. Uncommon: Hypotension, Tachycardia, Hypertension, Dyspnoea, Electrolyte disturbances, e.g. Hypocalcaemia, Dizziness, Oedema, Disturbances inhydration. Very common: Electrolyte disturbances, e.g. Hypokalaemia.
Not known: Encapsulating peritoneal sclerosis.
Prescribers should consult the summary of product characteristics in relation to other adverse reactions.
Pack size and price: 2000ml bag £12.00, 2500ml bag £13.00; sleep.safe, 5000ml bag £21.50 (excl VAT). **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, Nunn Brook Road, Huthwaite, Sutton-in-Ashfield, NG17 2HU
Date of revision: August 2023

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 or medinfo-uk@fmc-ag.com