PRESCRIBING INFORMATION

balance 1.5% glucose 1.75 mmol/l calcium, solution for peritoneal dialysis MA No: PL 13689/0005
balance 2.3% glucose 1.75 mmol/l calcium, solution for peritoneal dialysis MA No: PL 13689/0007
balance 4.25% glucose 1.75 mmol/l calcium, solution for peritoneal dialysis MA No: PL 13689/0006
balance 1.5% glucose 1.25 mmol/l calcium, solution for peritoneal dialysis MA No: PL 13689/0011
balance 2.3% glucose 1.25 mmol/l calcium, solution for peritoneal dialysis MA No: PL 13689/0013
balance 4.25% glucose 1.25 mmol/l calcium, solution for peritoneal dialysis MA No: PL 13689/0012

Composition:

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

Active substances in g/l	**balance 1.5%** glucose, **1.75** mmol/l calcium	**balance 2.3%** glucose, **1.75** mmol/l calcium	**balance 4.25%** glucose, **1.75** mmol/l calcium	**balance 1.5%** glucose, **1.25** mmol/l calcium	**balance 2.3%** glucose, **1.25** mmol/l calcium	**balance 4.25%** glucose, **1.25** mmol/l calcium
Sodium chloride	5.640	5.640	5.640	5.640	5.640	5.640
Sodium lactate solution (Sodium (S) Lactate)	7.85g (3.925g)	7.85g (3.925g)	7.85g (3.925g)	7.85g (3.925g)	7.85g (3.925g)	7.85g (3.925g)
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 (anhydrous glucose)	16.5g (15.0g)	25.0g (22.73g)	46.75g (42.5g)	16.5g (15.0g)	25.0g (22.73g)	46.75g (42.5g)

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

Active substances in mmol/l	**balance 1.5%** glucose, **1.75** mmol/l calcium	**balance 2.3%** glucose, **1.75** mmol/l calcium	**balance 4.25%** glucose, **1.75** mmol/l calcium	**balance 1.5%** glucose, **1.25** mmol/l calcium	**balance 2.3%** glucose, **1.25** mmol/l calcium	**balance 4.25%** glucose, **1.25** mmol/l calcium
Na^+	134	134	134	134	134	134
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^-	101.5	101.5	101.5	100.5	100.5	100.5
Lactate	35	35	35	35	35	35
Glucose	83.2	126.1	235.8	83.2	126.1	235.8
Theoretical osmolarity (mosm/l)	358	401	511	356	399	509
pH	7.0	7.0	7.0	7.0	7.0	7.0

Indications: End-stage (decompensated) chronic renal failure of any origin which can be 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 prescribed, patients will receive an infusion of 2000 ml solution per exchange 4 times a day. After a dwell time between 2 and 10 hours the solution will be drained. Adjustment of dosage, volume and number of exchanges will be necessary for individual patients. Paediatric population: 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 600-800ml/m^2 BSA with 4 (sometimes 3 or 5) exchanges per day. It can be increased up to 1000-1200ml/m^2 BSA depending on tolerance, age and residual renal function. **Automated peritoneal dialysis (APD) I**f a machine (sleep•safe cycler or PD-NIGHT cycler) is used for intermittent or continuous cyclic peritoneal dialysis, the use of larger bags is recommended providing more than one solution exchange. 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. The amount of fluid used is typically between 10 and 18 lts but can range from 6 to 30 lts. The cycler therapy at night is usually combined with 1 or 2 exchanges during the daytime. Paediatric population: The volume per exchange should be 800-1000 ml/m^2 BSA with 5-10 exchanges overnight. It can be increased up to 1400 ml/m^2 BSA depending on tolerance, age and residual renal function. There are no special dosage recommendations for the elderly.
Method and duration of administration: Before performing peritoneal dialysis at home the patient must be trained appropriately, must practice the technique and be shown to be proficient. The training should be performed by qualified personnel. The attending physician must ensure that the patient masters the handling techniques sufficiently before being discharged to carry out peritoneal dialysis at home. In case of any problems or uncertainty the attending physician should be contacted. **Continuous ambulatory peritoneal dialysis (CAPD): staysafe bag;** The solution bag is first warmed up to body temperature. The appropriate dose is infused in the peritoneal cavity using a peritoneal catheter over 5 - 20 minutes. Depending on physician's instructions, the dose should dwell in the peritoneal cavity for 2 to 10 hours (equilibrium time), and then be drained. **Automated peritoneal dialysis (APD):** sleepsafe bag: The connectors of the prescribed sleepsafe solution bags are inserted in the free sleepsafe tray ports and then automatically connected to the sleepsafe tubing set by the cycler. The cycler checks the bar codes of the solution bags and gives an alarm when the bags do not comply with the prescription stored in the cycler. After this check the tubing set can be connected to the patient's catheter extension and the treatment be started. The sleepsafe solution is automatically warmed up to body temperature by the sleepsafe cycler during the inflow into the abdominal cavity. **Contraindications:** For this specific peritoneal dialysis solution **balance 1.5%/2.3% glucose, 1.25 mmol/l calcium** must not be used in patients with lactic acidosis, severe hypokalaemia and severe hypocalcaemia. **balance 4.25% glucose, 1.25 mmol/l calcium** must not be used in patients with lactic acidosis, severe hypokalaemia, severe hypocalcaemia, hypovolaemia and arterial hypotension. **balance 1.5%/2.3% glucose, 1.75 mmol/l calcium** must not be used in patients with lactic acidosis, severe hypokalaemia and severe hypercalcaemia. **balance 4.25% glucose, 1.75 mmol/l calcium** must not be used in patients with lactic acidosis, severe hypokalaemia, severe hypercalcaemia, hypovolaemia and arterial hypotension. For peritoneal dialysis in general - recent abdominal surgery or injury, inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis), peritonitis, internal or external abdominal fistula, umbilical, inguinal or other abdominal hernia, intra-abdominal Tumours, pulmonary disease, sepsis, extreme hyperlipidaemia.

Special warnings and precautions for use: Encapsulating peritoneal sclerosis is considered to be a known, rare complication of peritoneal dialysis therapy which can infrequently lead to fatal outcome. The solution for peritoneal dialysis must not be used for intravenous infusion. This solution may only be administered after careful benefit-risk assessment in: **balance 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium -** patients with hyperparathyroidism: Therapy should include the administration of calcium-containing phosphate binders and/or vitamin D to ensure adequate enteral calcium supply. 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. **balance 1.5%/2.3%/4.25% glucose, 1.75 mmol/l calcium** - Hypercalcaemia, e.g. due to the administration of calcium-containing phosphate binders and/or vitamin D (a temporary or permanent change to a peritoneal dialysis solution with a lower calcium concentration should be considered). **balance 1.5%/2.3%/4.25% glucose, 1.25/1.75 mmol/l calcium -** loss of electrolytes due to vomiting and/or diarrhoea (a temporary change to a peritoneal dialysis solution containing potassium might then become necessary). 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 together with dietary counselling. patients with large polycystic kidneys - A loss of proteins, amino acids, and water-soluble vitamins occurs during peritoneal dialysis. To avoid deficiencies an adequate diet or supplementation should be ensured. **Elderly -** The increased incidence of hernia should be considered in the elderly prior to the start of peritoneal dialysis.
Interactions: Effect of balance on other medications: 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.
Undesirable effects: **peritoneal dialysis solutions & treatment mode:** Endocrine disorders **- balance 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium** - Secondary hyperparathyroidism with potential disturbances of the bone metabolism (not known). Metabolism and nutrition disorders- Increased blood sugar levels (common ≥1/100 to <1/10), Hyperlipidaemia (common), Increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution (common). Cardiac and vascular disorders - Tachycardia (uncommon ≥1/1000 to <1/100), Hypotension (uncommon), Hypertension (uncommon). Respiratory, thoracic and mediastinal disorders **-** Dyspnoea (uncommon). Renal and urinary disorders **- balance 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium -** Electrolyte disturbances, e.g. hypokalaemia (very common ≥1/10), Hypocalcaemia (uncommon), **balance 1.5%/2.3%/4.25% glucose, 1.75 mmol/l calcium -** Electrolyte disturbances, e.g. hypokalaemia (very common), Hypercalcaemia in combination with an increased calcium uptake, e.g. by the administration of calcium-containing phosphate binders (common). **Treatment mode**: Encapsulating peritoneal sclerosis (not known).
Presentations: *staysafe:* The stay•safe system contains the double chamber bag system, a tubing system made of polyolefines, a system connector (DISC) with a rotable switch (polypropylene) and a drainage bag, also made of polyolefine-based multi layer film. sleepsafe: The *sleep•safe* system contains the double chamber bag system and a bag connector which consists of polypropylene.
(Please refer to the full Summary of Product Characteristics for detailed information)
Legal Category: POM
Marketing Authorisation Holder: Fresenius Medical Care Deutschland GmbH D-61346 Bad Homburg Germany.
Presentation and NHS cost (excl. VAT): stay.safe balance 2000ml bag £7.50, 2500ml bag £8.30, sleep.safe balance 5000ml bag £11.60
Date of revision: November 2022

FRESENIUS MEDICAL CARE

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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 445 215

Date of preparation: November 2022, Job bag UK/PD/BAL/0820/0001

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 22° 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

PRESCRIBING INFORMATION
(Please refer to the full Summary of Product Characteristics before prescribing)

CAPD 17, solution for peritoneal dialysis MA No: PL 13689/0001
CAPD 19, solution for peritoneal dialysis MA No: PL 13689/0003

Presentations:

Stay safe:
The stay safe system is provided as a double bag system consisting of a non-PVC solution bag made of a multi-layer polyolefine based foil, a tubing system also made of polyolefines, a system connector (DISC, polypropylene), a drainage bag and an outer bag, also made of polyolefine multi-layer film.
Sleep safe:
The sleep safe system is provided as a single bag system consisting of a non- PVC solution bag made of a multi-layer polyolefine based foil, a tubing system, a bag connector both also made of polyolefines and an injection port made of polyolefine/synthetic rubber.

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

Active substances in g/l	CAPD 17	CAPD 19
Sodium chloride	5.786	5.786
Sodium lactate (as sodium lactate solution)	7.85	7.85
Calcium chloride dihydrate	0.1838	0.1838
Magnesium chloride hexahydrate	0.1017	0.1017
Glucose monohydrate	16.5	25.0

Active substances in mmol/l	CAPD 17	CAPD 19
Na^+	134	134
Ca^{2+}	1.25	1.25
Mg^{2+}	0.5	0.5
Cl^-	102.5	102.5
Lactate	35	35
Glucose	83.2	126.1
Theoretical osmolarity (mosm/l)	356	399
pH	5.5	

Excipients: Water for injections, hydrochloric acid, sodium hydroxide.
Indications: End-stage (decompensated) chronic renal failure of any origin which can be 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. Unless otherwise prescribed, patients will receive an infusion of 2000 ml solution per exchange 4 times a day. After a dwell time between 2 and 10 hours the solution will be drained. In children the solution volume per exchange should be prescribed according to age and body surface area (BSA). If a machine (sleep-safe cycler) is used for intermittent or continuous cyclic peritoneal dialysis, larger volume bags (e.g. 5000 ml) providing more than one solution exchanges are used. The cycler performs the solution exchanges according to the medical prescription stored in the cycler.
Contraindications: Solution related: Solutions with 1.5%/2.3% glucose, 1.25 mmol/l calcium: must not be used in patients with lactic acidosis, severe hypokalaemia and severe hypocalcaemia. Additionally, solutions with 2.3% glucose: hypovolaemia and arterial hypotension. Due to the content of fructose, this medicinal product is not suitable for patients with fructose intolerance (hereditary fructose intolerance). Treatment related: 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), peritonitis, internal/external abdominal fistula, abdominal hernia, intra-abdominal tumours, ileus, pulmonary disease (especially pneumonia), sepsis, extreme hyperlipidaemia, in rare cases of uraemia, which cannot be managed by peritoneal dialysis, physical or mental incapability to perform peritoneal dialysis.
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. The ready-to-use solution must be used within 24 hours after mixing. Do not store above 25ºC. Not to be used for Intravenous Infusion. These solutions should only be administered after careful benefit-risk assessment in: Loss of electrolytes due to vomiting and/or diarrhoea (a temporary change to a peritoneal dialysis solution containing potassium might then become necessary). Hypocalcaemia: It may be necessary to use peritoneal dialysis solutions with a higher calcium concentration either temporarily or permanently, in case an adequate enteral supply with calcium by calcium containing phosphate binders and/or vitamin D is not possible. Hyperparathyroidism: The therapy should comprise the administration of calcium-containing phosphate binders and/or vitamin D to ensure adequate enteral calcium supply. Patients receiving digitalis therapy: Regular monitoring of the serum potassium level is mandatory. Encapsulating peritoneal sclerosis is considered to be a known, rare complication of peritoneal dialysis therapy which can infrequently lead to fatal outcome.
Fertility, pregnancy and lactation: CAPD/DPCA 17 & CAPD/DPCA 19 should not be used during pregnancy unless the clinical condition of the woman requires treatment. No data on excretion in human milk or on human fertility.
Interaction with other medicinal products: In diabetic patients the daily dose of insulin or oral hypoglycaemic medicinal products must be adjusted to take account of the increased glucose load.
Overdose: The most likely consequence of an overdosage is dehydration.
Side effects: peritoneal dialysis solutions & treatment mode: Endocrine disorders: Secondary hyperparathyroidism with potential disturbances of the bone metabolism. Metabolism and nutrition disorders: common (≥ 1/100 to <1/100); Increased blood sugar levels, increase in body weight due to the continuous uptake of glucose from peritoneal dialysis solution, hyperlipidaemia or deterioration of pre-existing hyperlipidaemia. Cardiac and vascular disorders: uncommon (≥1/1,000 to <1/100): Tachycardia; hypotension; hypertension. Respiratory disorders: (not known): Dyspnoea caused by the elevated diaphragm General disorders and administration site conditions: uncommon (≥1/1,000 to <1/100): dizziness, oedema. Gastrointestinal disorders: Diarrhoea (uncommon ≥1/1,000 to <1/100); constipation (uncommon ≥1/1,000 to <1/100); hernia (very common ≥1/10); abdominal distension and sensation of fullness (common ≥1/100 to <1/10). Renal disorders: Electrolyte disturbances, e.g. hypokalaemia (very common ≥1/10), hypocalcaemia (uncommon ≥1/1,000 to <1/100). General disorders and administration site conditions: Dizziness (uncommon), Oedema (uncommon). Disturbances in fluid balance (uncommon) indicated either by a rapid decrease (dehydration) or increase (overhydration) in body weight. Severe dehydration might occur when using solutions of higher glucose concentration. **Treatment mode**: Infections and infestations - Peritonitis (very common) indicated by a cloudy effluent. Later abdominal pain, fever, and general malaise may develop or, in very rare cases, sepsis. The patient should seek medical advice immediately. Skin exit site and tunnel infections (very common) indicated by redness, oedema, exudations, crusts and pain at the catheter exit site. Respiratory, thoracic and mediastinal disorders - Dyspnoea caused by the elevated diaphragm (not known), Gastrointestinal disorders- Hernia (very common), Abdominal distension and sensation of fullness (common), Diarrhoea (uncommon), Constipation (uncommon), Encapsulating peritoneal sclerosis (not known). Injury, poisoning and procedural complications - In- and outflow disturbances of the dialysis solution (common), Shoulder pain (common).
(Please refer to the Summary of Product Characteristics for detailed information)
Legal Category: POM
Marketing Authorisation Holder: Fresenius Medical Care Deutschland GmbH. 61346 Bad Homburg v.d.H. Germany.
Pack size and NHS price: staysafe 2000ml bag £4.24, sleepsafe 5000ml bag £9.70 (excl. VAT).
Last 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.

FRESENIUS MEDICAL CARE

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Date of preparation: August 2023
Job bag UK-PD-000005