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)** If 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
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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

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