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 25₀C. 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).
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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 or medinfo-uk@fmc-ag.com.

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