SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

balance 2.3% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

balance 1.5%/2.3%/4.25% glucose, 1.25/1.75 mmol/l calcium is 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.

BEFORE RECONSTITUTION

1 litre of acidic glucose based electrolyte solution contains:

	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	*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
Calcium chloride dihydrate	0.3675 g	0.3675 g	0.3675 g	0.5145 g	0.5145 g	0.5145 g
Sodium chloride	11.279 g	11.279 g	11.279 g	11.279 g	11.279 g	11.279 g
Magnesium chloride hexahydrate	0.2033 g	0.2033 g	0.2033 g	0.2033 g	0.2033 g	0.2033 g
Glucose monohydrate (anhydrous glucose)	33.0 g (30.0 g)	50.0 g (45.46 g)	93.5 g (85.0 g)	33.0 g (30.0 g)	50.0 g (45.46 g)	93.5 g (85.0 g)

1 litre of alkaline lactate solution contains:
Sodium (S)-lactate solution 15.69 g
(sodium (S)lactate 7.85 g)

AFTER RECONSTITUTION

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

	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	*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
Calcium chloride dihydrate	0.1838 g	0.1838 g	0.1838 g	0.2573 g	0.2573 g	0.2573 g
Sodium chloride	5.640 g	5.640 g	5.640 g	5.640 g	5.640 g	5.640 g
Sodium (S)-lactate solution (sodium (S)-lactate)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)
Magnesium chloride hexahydrate	0.1017 g	0.1017 g	0.1017 g	0.1017 g	0.1017 g	0.1017 g
Glucose monohydrate (anhydrous glucose)	16.5 g (15.0 g)	25.0 g (22.73 g)	46.75 (42.5 g)	16.5 g (15.0 g)	25.0 g (22.73 g)	46.75 (42.5 g)

	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	*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
Ca^{2+}	1.25 mmol	1.25 mmol	1.25 mmol	1.75 mmol	1.75 mmol	1.75 mmol
Na^{+}	134 mmol	134 mmol	134 mmol	134 mmol	134 mmol	134 mmol
Mg^{2+}	0.5 mmol	0.5 mmol	0.5 mmol	0.5 mmol	0.5 mmol	0.5 mmol
Cl^{-}	100.5 mmol	100.5 mmol	100.5 mmol	101.5 mmol	101.5 mmol	101.5 mmol
Lactate	35 mmol	35 mmol	35 mmol	35 mmol	35 mmol	35 mmol
Glucose	83.2 mmol	126.1 mmol	235.8 mmol	83.2 mmol	126.1 mmol	235.8 mmol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for peritoneal dialysis
Double chamber bag containing clear and colourless aqueous solutions

For the ready-to-use solution:

	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	*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
Theoretical osmolarity	356 mOsm/l	399 mOsm/l	509 mOsm/l	358 mOsm/l	401 mOsm/l	511 mOsm/l
pH ≈	7.0	7.0	7.0	7.0	7.0	7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

End-stage (decompensated) chronic renal failure of any origin which can be treated with peritoneal dialysis.

4.2 Posology and method of administration

Posology

This solution is indicated exclusively for intraperitoneal use.
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 four 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.

If dilation pain occurs at the commencement of peritoneal dialysis, the solution volume per exchange should be temporarily reduced to 500-1500 ml.

In large patients, and if residual renal function is lost, an increased volume of dialysis solution will be necessary. In these patients, or patients who tolerate larger volumes, a volume of 2500-3000 ml solution per exchange may be given.

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 600-800 ml/m^2 BSA with 4 (sometimes 3 or 5) exchanges per day. It can be increased up to 1000-1200 ml/m^2 BSA depending on tolerance, age and residual renal function.

Automated peritoneal dialysis (APD)
A machine (cycler) is used for intermittent or continuous cyclic peritoneal dialysis. The use of larger bags is recommended providing more than one solution exchange. The cycler performs the solution exchanges according to the medical prescription stored in the cycler.

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 l but can range from 6 to 30 l. 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.

Peritoneal dialysis solutions with a high glucose concentration (2.3% or 4.25%) are used when the body weight is above the desired dry weight. The withdrawal of fluid from the body increases in relation to the glucose concentration of the peritoneal dialysis solution. These solutions should be used cautiously to handle the peritoneal membrane with care, to prevent dehydration and in order to keep the glucose burden as low as possible.

Peritoneal dialysis is a long-term therapy involving repeated administrations of single solutions.

balance 1.5% glucose, 1.75 mmol/l calcium contains 15 g glucose in 1000 ml solution.

Method 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.
Dialysis using the prescribed doses should be performed daily and should be continued for as long as renal function substitution therapy is required.

Continuous ambulatory peritoneal dialysis (CAPD): *stay•safe* bag
The solution bag is first warmed up to body temperature. For details see section 6.6.

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): *sleep•safe* bag
The connectors of the prescribed *sleep•safe* solution bags are inserted in the free tray ports and then automatically connected to the 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 *sleep•safe* solution is automatically warmed up to body temperature by the cycler during the inflow into the abdominal cavity. Dwell times and selection of glucose concentrations are carried out according to the medical prescription stored in the cycler (for more details please refer to the operating instructions of the cycler).

Automated peritoneal dialysis (APD): Safe•Lock bag
The connectors of the prescribed Safe•Lock solution bags are connected manually to the tubing set of the cycler. The Safe•Lock solution is placed on the heater plate of the cycler for warming of the solution that will be transferred to the abdominal cavity of the patient during the treatment. Dwell times and selection of glucose concentrations are carried out according to the medical prescription stored in the cycler (for more details please refer to the operating instructions of the cycler).

Depending on the required osmotic pressure, balance 1.5% glucose, 1.75 mmol/l calcium can be used sequentially with other peritoneal dialysis solutions with higher glucose content (i.e., with higher osmolarity).

4.3 Contraindications

For this specific peritoneal dialysis solution

balance 1.5%/2.3% glucose, 1.25 mmol/l calcium	*balance* 4.25% glucose, 1.25 mmol/l calcium	*balance* 1.5%/2.3% glucose, 1.75 mmol/l calcium	*balance* 4.25% glucose, 1.75 mmol/l calcium
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

Peritoneal dialysis should not be commenced if any of the following are present:
- 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 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 cannot be managed by peritoneal dialysis,
- cachexia and severe weight loss, particularly in cases where ingestion of adequate protein is not guaranteed,
- patients who are physically or mentally incapable of performing peritoneal dialysis as instructed by the physician.

If any of the above mentioned disorders develops during the peritoneal dialysis, the attending physician will have to decide on how to proceed.

4.4 Special warnings and precautions for use

The solution for peritoneal dialysis must not be used for intravenous infusion.

This solution may only be administered after careful benefit-risk assessment in:
- 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).
- 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 (see section 4.5). 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.

The transport characteristics of the peritoneal membrane may change during long-term peritoneal dialysis primarily indicated by a loss of ultrafiltration. In severe cases peritoneal dialysis must be stopped and haemodialysis commenced.

Regular 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, blood gases 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.

The effluent should be checked for clarity and volume. Turbidity and/or abdominal pain are indicators of peritonitis.

Encapsulating peritoneal sclerosis is considered to be a known, rare complication of peritoneal dialysis therapy which can infrequently lead to fatal outcome.

Elderly

The increased incidence of hernia should be considered in the elderly prior to the start of peritoneal dialysis.

4.5 Interaction with other medicinal products and other forms of interaction

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 be 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 (see section 4.4).
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 insulin or oral hypoglycaemic medicinal products must be adjusted to take account of the increased glucose load.

The concomitant administration of calcium-containing medicinal products or vitamin D may cause hypercalcaemia.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of *balance* solutions in pregnant women. Data from animal studies are lacking (see section 5.3). When considering peritoneal dialysis as a possible therapy during pregnancy, the benefit of therapy should be weighed against the potential risks and complications for mother and child.

Breastfeeding

The components of *balance* are excreted in human milk. With adequate therapy, however, no adverse reactions are expected in the child. A temporary interruption of breastfeeding may be considered, taking into account the benefit of breastfeeding for the child and the benefit of therapy for the mother.

Fertility

There are no clinical data available on the possible effects on fertility. In therapeutic use, however, no effects are expected on fertility.

4.7 Effects on ability to drive and use machines

balance 2.3% glucose, 1.75 mmol/l calcium has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

balance 1.5% glucose, 1.75 mmol/l calcium is an electrolyte solution the composition of which is similar to blood. In addition, the solution has a neutral pH which is similar to the physiological pH value.

Possible adverse reactions may result from the peritoneal dialysis itself or may be induced by the peritoneal dialysis solution.

The adverse drug reactions are ranked under the headings of reporting frequency, using the following convention:

Very common	≥1/10
Common	≥1/100 to <1/10
Uncommon	≥1/1 000 to <1/100
Rare	≥1/10 000 to <1/1 000
Very rare	<1/10 000
Not known	cannot be estimated from the available data

Potential adverse reactions of the peritoneal dialysis solution

Metabolism and nutrition disorders
- Increased blood sugar levels (common)
- Hyperlipidaemia (common)
- Increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution (common)

Cardiac disorders
- Tachycardia (uncommon)

Vascular disorders
- Hypotension (uncommon)
- Hypertension (uncommon)

Respiratory, thoracic and mediastinal disorders
- Dyspnoea (uncommon)

Renal and urinary disorders
- 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)

General disorders
- Dizziness (uncommon)
- Oedema (uncommon)
- Disturbances in hydration (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.

Potential adverse reactions of the 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. The bag with the cloudy effluent should be closed with a sterile cap and assessed for microbiological contamination and white blood cell count.
- Skin exit site and tunnel infections (very common).
  In case of skin exit site and tunnel infections the attending physician should be consulted as soon as possible.
- Sepsis (very rare)

Respiratory, thoracic and mediastinal disorders
- Shoulder pain (common)
- 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)

General disorders and administration/catheter site conditions
- Redness, oedema, exudations, crusts and pain at the catheter exit site (very common)
- In- and outflow disturbances of the dialysis solution (common)
- General malaise (not known)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No emergency situations in connection with overdose have been reported.

Any excess of dialysis solution infused into the peritoneal cavity can easily be drained into the drainage bag. In case of too frequent exchanges, dehydration and/or electrolyte disturbances might result, which necessitate immediate medical attention. If an exchange has been forgotten, then the attending physician or dialysis centre in charge should be contacted.

Incorrect balancing can lead to hyper- or dehydration and electrolyte disturbances.

The most likely consequence of an overdosage with *balance* 1.5 glucose, 1.75 mmol/l calcium is dehydration.
Underdosage, interruption of treatment or discontinuation of treatment may lead to life-threatening hyperhydration with peripheral oedema and cardiac decompensation and/or other symptoms of uraemia, which may endanger life.

The generally accepted rules for emergency care and intensive therapy must be applied. The patient may require immediate haemodialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Peritoneal dialytics, hypertonic solutions
ATC code: B05D B

balance 1.5%/2.3%/4.25% glucose, 1.25/1.75 mmol/l calcium is a lactate-buffered, glucose-containing electrolyte solution indicated for intraperitoneal administration for the treatment of end-stage renal failure of any origin by continuous ambulatory

peritoneal dialysis (CAPD).

The characteristic of continuous ambulatory peritoneal dialysis (CAPD) is the more or less continuous presence of usually 2 litres of dialysis solution in the peritoneal cavity. This dialysis solution is replaced by fresh solution three to five times a day.

The basic principle behind every peritoneal dialysis technique is the use of the peritoneum as a semi-permeable membrane allowing the exchange of solutes and water between the blood and the dialysis solution by diffusion and convection according to their physico-chemical properties.

The electrolyte profile of the solution is basically the same as that of physiological serum, although it has been adapted (e.g. the potassium content) for use in uraemic patients to enable renal function substitution therapy by means of intraperitoneal substances and fluid exchange.

balance 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium
The calcium concentration of this dialysis solution is 1.25 mmol/l, which has been shown to reduce the risk of hypercalcaemia during concomitant treatment with calcium containing phosphate binders and/or vitamin D.

Substances which are normally eliminated with the urine, like uraemic waste products, such as urea and creatinine, inorganic phosphate, uric acid, other solutes and water, are removed from the body into the dialysis solution. The fluid balance can be maintained by the administration of different glucose-concentrations in the solution, effecting the fluid removal (ultrafiltration).
Metabolic acidosis secondary to end-stage renal failure is counterbalanced by the presence of lactate in the solution. The complete metabolism of lactate results in the generation of bicarbonate.

5.2 Pharmacokinetic properties

Uraemic waste products (e.g. urea, creatinine, uric acid), inorganic phosphate and electrolytes like sodium, potassium, calcium and magnesium are removed from the body to the dialysis solution by diffusion and/or convection.

Glucose in the dialysate is used as an osmotic agent in *balance* 1.5% glucose, 1.75 mmol/l calcium. It is slowly absorbed, reducing the diffusion gradient between dialysis solution and extracellular fluid. The ultrafiltration is maximal at the beginning of the dwell time, reaching a peak after about two to three hours. Later absorption starts with a progressive loss of ultrafiltrate.

After 4 hours the ultrafiltrate averages 100 ml with a 1.5%, 400 ml with a 2.3%, and 800 ml with a 4.25% glucose solution. During the dialysis period of six hours 60 to 80% of dialysate glucose is absorbed.

Lactate used as the buffering agent is almost completely absorbed after a 6-hour dwell time. In patients with a normal hepatic function lactate is rapidly metabolised demonstrated by normal values of intermediate metabolites.

The transfer of calcium depends on the glucose concentration in the dialysis solution, the effluent volume, the serum ionised calcium and the calcium concentration in the dialysis solution. The higher the glucose concentration, effluent volume and serum calcium concentration, and the lower the calcium concentration in the dialysis solution, the higher is the calcium transfer from the patient to the dialysate.

5.3 Preclinical safety data

No preclinical toxicity studies with *balance* 1.5%/2.3%/4.25% glucose, 1.25/1.75 mmol/l calcium have been carried out. The electrolytes and glucose included in *balance* are physiological components in human plasma. Thus, no toxic effects are expected to occur as long as the indications, contraindications and dosage recommendations are adequately observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Hydrochloric acid
Sodium hydroxide
Sodium hydrogen carbonate

6.2 Incompatibilities

Because of the risk of incompatibility and of contamination medicinal products must only be added when prescribed by a physician.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

Shelf life as packed for sale: 2 years.

Shelf life of the ready-to-use solution prepared as described in section 6.6 and without any additional medicinal products: Chemical and physical in-use stability has been demonstrated for 24 hours at 20 °C.

6.4 Special precautions for storage

Do not store below 4°C

6.5 Nature and contents of container

Double-chamber bag system consisting of a non-PVC double-chamber solution bag made of polyolefine, with an injection port. It is wrapped in a protective bag, also made of polyolefine.
One chamber of the solution bag contains the alkaline lactate solution; the other chamber contains the acidic glucose-based electrolyte solution (ratio 1:1). Mixing of both solutions by opening the middle seam between the two chambers results in the ready-to-use solution.

There are three versions of the container available as follows:

stay•safe:
The *stay•safe* system is provided as a double-bag system consisting of the double-chamber solution bag, a transfer tubing system made of polyolefines, a system connector (DISC) with a rotable switch (polypropylene) and a drainage bag, also made of polyolefine.

sleep•safe:
The *sleep•safe* system is provided as a single-bag system consisting of the double-chamber solution bag, a transfer tubing system made of polyolefines and a bag connector made of polypropylene.

Safe•Lock:
The Safe•Lock system is provided as a single-bag system consisting of the double-chamber solution bag and a Safe•Lock connector made of polycarbonate.

Pack sizes:
stay•safe
4 bags each containing 2000 ml
4 bags each containing 2500 ml
4 bags each containing 3000 ml

sleep•safe
4 bags each containing 3000 ml
2 bags each containing 5000 ml
2 bags each containing 6000 ml

Safe•Lock
2 bags each containing 5000 ml
2 bags each containing 6000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

For single use only. Any unused portion of the solution is to be discarded.

***stay•safe* system** for continuous ambulatory peritoneal dialysis (CAPD):
The solution bag is first warmed up to body temperature. For bags with a volume up to 3000 ml this should be done using an appropriate bag warmer. The heating time depends on bag volume and the used bag warmer (for a 2000 ml bag with a starting temperature of 22 °C usually 120 min.). The temperature control is done automatically and is set to 39 °C ± 1 °C. More detailed information can be obtained from the operating instructions of the bag warmer. Use of microwaves is not recommended due to the risk of local overheating.

1. Preparation of the solution
   ◗ Check the warmed solution bag (label, expiry date, clearness of the solution, bag and overwrap not damaged, integrity of peel seams). ◗ Place the bag on a solid surface. ◗ Open the overwrap of the bag and the packaging of the disinfection cap/closure cap. ◗ Wash your hands with an antimicrobial washing lotion. ◗ Roll up the bag, which is lying on the overwrap, from one of the side edges until the middle seam opens. The solutions in the two chambers are mixed automatically. ◗ Now roll up the bag from the upper edge until the peel seam of the lower triangle is completely open. ◗ Check that all peel seams are completely open. ◗ Check that the solution is clear and that the bag is not leaking.
2. Preparation of the bag exchange
   ◗ Hang the solution bag in the upper hole of the infusion pole, unroll the tubing line of the solution bag, and place the DISC into the organizer. After unrolling the tubing line to the drainage bag, hang the drainage bag in the lower hole of the infusion pole. ◗ Place catheter connector into one of the two inserts of the organizer. ◗ Place the new disinfection cap/closure cap into the other free insert. ◗ Disinfect your hands and remove the protection cap of the DISC. ◗ Connect catheter connector to the DISC.
3. Outflow
   ◗ Open the clamp on the extension. The outflow starts. ◗ Position (
4. Flush
   ◗ After completion of outflow flush fresh solution into the drainage bag (approx. 5 seconds). ◗ Position ((
5. Inflow
   ◗ Start inflow by turning the control switch to ◗ Position ∗)(
6. Safety step
   ◗ Automated closing of the catheter extension with the PIN. ◗Position ((((
7. Disconnection
   ◗ Remove the protection cap from the new disinfection cap/closure cap and screw it onto the old one. ◗ Screw the catheter connector off the DISC and screw the catheter connector to the new disinfection cap/closure cap.
8. Closure of the DISC
   ◗ Close the DISC with the open end of the protection cap, which has remained in the other insert of the organizer.

9. Check the drained dialysate for clarity and weight and if the effluent is clear discard it.

***sleep•safe* system** for automated peritoneal dialysis (APD)
(for the set-up of the *sleep•safe* system please refer to its operating instructions):

3000 ml *sleep•safe* system:
1. Preparation of the solution: see *stay•safe* system
2. Unroll tubing of bag.
3. Remove the protection cap.
4. Insert bag connector in free tray port of the cycler.
5. The bag is now ready for use with the *sleep•safe* set.

5000 ml and 6000 ml *sleep•safe* system:
1. Preparation of the solution
   ➧ Check the solution bag (label, expiry date, clearness of the solution, bag, and overwrap not damaged, peel seams intact). ➧ Place the bag on a solid surface. ➧ Open the overwrap of the bag. ➧ Wash your hands with an antimicrobial washing lotion. ➧ Unfold middle peel seam and bag connector. ➧ Roll up the bag, which is lying on the overwrap, from the diagonal end towards the bag connector. The middle peel seam will open. ➧ Continue until the peel seam of the small chamber opens as well. ➧ Check that all peel seams are completely open. ➧ Check that the solution is clear and that the bag is not leaking.
2. Unroll tubing of bag.
3. Remove the protection cap.
4. Insert bag connector in free tray port of the cycler.
5. The bag is now ready for use with the *sleep•safe* set.

Safe•Lock system for automated peritoneal dialysis (APD)
(for the set-up of the Safe•Lock system please refer to its operating instructions):
1. Preparation of the solution: see 5000 and 6000 ml *sleep•safe* system
   ➧ Remove protective cap of the connector from the connecting line.
2. Connect lines to the bag.
3. Break the inner lock by bending the line and the PIN by more than 90° to both sides.
4. The bag is now ready for use.

See also section 4.2.

Handling

The ready-to-use solution should be used immediately, but if this is not possible within a maximum of 24 hours after mixing (see also section 6.3).

Plastic containers may occasionally be damaged during transport or storage. This can result in a contamination with growth of microorganisms in the dialysis solution. Thus, all containers should be carefully inspected for damage prior to connection of the bag and prior to use of the peritoneal dialysis solution. Any damage, even minor, to connectors, at the closure, container welds and corners must be noted because of possible contamination. Damaged bags or bags with cloudy content should never be used.

This solution must only be used if the solution for dialysis is clear and the container undamaged.

The overwrap should only be removed before administration.

Do not use before the two solutions have been mixed.

Aseptic conditions must be maintained during dialysate exchange in order to reduce the risk of infection.

Addition of medication to the peritoneal dialysis solution:

Medicinal products must be added under aseptic conditions only when medically prescribed. Because of the risk of incompatibility between the dialysis solution and the added medicinal products only the following medicinal products may be added up to the mentioned concentration if indicated by the attending physician: heparin 1000 I.U./l, insulin 20 I.U./l, vancomycin 1000 mg/l, teicoplanin 400 mg/l, cefazolin 500 mg/l, ceftazidime 250 mg/l, gentamicin 8 mg/l. After thorough mixing and checking for the absence of any turbidity or particles the peritoneal dialysis solution must be used immediately (no storage).

7 MARKETING AUTHORISATION HOLDER

Fresenius Medical Care Deutschland GmbH
Else-Kröner-Straße. 1
61352 Bad Homburg v.d.H.
Germany

8. MARKETING AUTHORISATION NUMBER

PL 13689/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/08/2003 /17/11/2009

10 DATE OF REVISION OF THE TEXT

07/01/2025