SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CAPD 2 peritoneal dialysis solution
CAPD 3 peritoneal dialysis solution
CAPD 4 peritoneal dialysis solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 litre contains:

	CAPD 2	**CAPD 3**	**CAPD 4**
Calcium chloride dihydrate	0.2573 g	0.2573 g	0.2573 g
Sodium chloride	5.786 g	5.786 g	5.786 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)
Magnesium chloride hexahydrate	0.1017 g	0.1017 g	0.1017 g
Glucose monohydrate (Glucose)	16.5 g (15.0 g) (up to 0.75 g fructose)	46.75 g (42.5 g) (up to 2.1 g fructose)	25.00 g (22.73 g) (up to 1.1 g fructose)
Ca^{2+}	1.75 mmol/l	1.75 mmol/l	1.75 mmol/l
Na^{+}	134 mmol/l	134 mmol/l	134 mmol/l
Mg^{2+}	0.5 mmol/l	0.5 mmol/l	0.5 mmol/l
Cl^{-}	103.5 mmol/l	103.5 mmol/l	103.5 mmol/l
(S)-lactate	35 mmol/l	35 mmol/l	35 mmol/l
Glucose	83.2 mmol/l	235.8 mmol/l	126.1 mmol/l

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for peritoneal dialysis
Clear, colourless to slightly yellow solution

For	CAPD 2	CAPD 3	CAPD 4
Theoretical osmolarity	358 mOsm/l	511 mOsm/l	401 mOsm/l

pH ≈ 5.5

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For use in patients with end-stage (decompensated) chronic renal failure of any origin being maintained on peritoneal dialysis.

4.2 Posology and method of administration

Posology

CAPD 2/3/4 is exclusively indicated 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 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 treatment, the solution volume per exchange should be 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 in patients who tolerate larger volumes, a dose 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 of BSA with 4 (sometimes 3 or 5) exchanges per day. It can be increased to 1000-1200 ml/m^2 of 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, larger volume bags (e.g. 5000 ml) providing more than one solution exchange are used. The cycler performs the solution exchanges according to the medical prescription stored in the *sleep•safe* 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 of BSA, with 5-10 exchanges overnight. It can be increased to 1400 ml/m^2 BSA depending on tolerance, age and residual renal function.

There are no special dosage recommendations for elderly patients.

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

Method and duration of administration

Patients must be trained appropriately, must practice the technique and be shown to be proficient at performing peritoneal dialysis before performing it at home. The training should be performed by qualified personnel. The attending physician must ensure that the patient masters the handling techniques sufficiently before the patient performs 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.
Peritoneal dialysis should be continued for as long as renal function substitution therapy is required.

Continuous ambulatory peritoneal dialysis (CAPD): *stay•safe* bag
The solution is first warmed to body temperature. For details, see 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 – 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 *sleep•safe* tray ports and then automatically connected to the *sleep•safe* 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 *sleep•safe* 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 *sleep•safe* cycler).

Automated peritoneal dialysis (APD): *safe•ock* bag
The connectors of the prescribed *safe•lock* solution bags are connected manually to the tubing set of PD-*NIGHT* cycler. One bag of *safe•lock* solution is placed on the heater plate of the cycler for warming of all 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 PD-*NIGHT* cycler).

CAPD 2:
Depending on the required osmotic pressure, CAPD 2 can be used sequentially with other peritoneal dialysis solutions with a higher glucose content (i.e. with higher osmolarity).
CAPD 3:
Depending on the required osmotic pressure, CAPD 3 can be used sequentially with other peritoneal dialysis solutions with a lower glucose content (i.e. with lower osmolarity).
CAPD 4:
Depending on the required osmotic pressure, CAPD 4 can be used sequentially with other peritoneal dialysis solutions with a higher or lower glucose content (i.e. with higher or lower osmolarity).

4.3 Contra-indications

For these specific peritoneal dialysis solutions

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
CAPD 2 must not be used in patients with lactic acidosis, severe hypokalaemia, and severe hypercalcaemia.
CAPD 3 must not be used in patients with lactic acidosis, severe hypokalaemia, severe hypercalcaemia, hypovolaemia and arterial hypotension.
CAPD 4 must not be used in patients with lactic acidosis, severe hypokalaemia and severe hypercalcaemia.

Due to the content of fructose, this medicinal product is not suitable for patients with fructose intolerance (hereditary fructose intolerance). A non-recognised hereditary fructose intolerance must be ruled out prior to administration to children and infants.

For peritoneal dialysis treatment in general

A peritoneal dialysis treatment should not be started in case of:

- recent abdominal surgery or injury, a history of abdominal operations with fibrous adhesions, severe abdominal burns, abdominal 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,
- rare cases of uraemia, which cannot be managed by peritoneal dialysis,
- cachexia and severe weight loss, particularly in cases where the intake of adequate protein cannot be guaranteed
- patients who are physically or mentally incapable of performing peritoneal dialysis as instructed by the physician.

If any of the aformentioned conditions develops during the peritoneal dialysis treatment, the attending physician shall 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.

CAPD 2/3/4 should only be administered after careful benefit-risk assessment in:

- loss of electrolytes due to vomiting and/or diarrhoea (a temporary switch to peritoneal dialysis solution containing potassium may then become necessary).
- hypercalcaemia, e.g. resulting from high doses of calcium-containing phosphate binders and/or vitamin D, a temporary or permanent switch to a solution with a lower calcium content may be necessary.
- patients receiving digitalis therapy: regular monitoring of the serum potassium level is mandatory. Severe hypokalaemia may require the use of a potassium-containing dialysis solution together with dietary counselling.

Peritoneal dialysis solutions with a high glucose concentration (2.3 % or 4.25 %) should be used cautiously to protect the peritoneal membrane, to prevent dehydration and to reduce the high glucose intake. CAPD solution is not biocompatible.

A loss of proteins, amino acids and water-soluble vitamins occurs during peritoneal dialysis. To avoid deficiencies, an adequate diet or dietary supplementats should be ensured.

The peritoneal membrane transport characteristics 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 hyper- and dehydration,
- serum sodium, potassium, calcium, magnesium, phosphate levels, acid-base balance and blood proteins,

- serum creatinine and urea,
- blood sugar,
- parathormone and other indicators of bone metabolism,
- residual renal function in order to adjust the peritoneal dialysis treatment.

CAPD 2 contains 15 g glucose in 1000 ml solution. Depending on the dosage instructions and on the used pack size, up to 38 g glucose (CAPD: 2500 ml *stay•safe*) or up to 90 g glucose (APD: 6000 ml *sleep•safe* or *safe•lock*) are supplied to the body with each bag. This should be taken into account in patients with diabetes mellitus.
CAPD 3 contains 42.5 g glucose in 1000 ml solution. Depending on the dosage instructions and on the used pack size, up to 106 g glucose (CAPD: 2500 ml *stay•safe*) or up to 255 g glucose (APD: 6000 ml *sleep•safe* or *safe•lock*) are supplied to the body with each bag. This should be taken into account in patients with diabetes mellitus.
CAPD 4 contains 22.73 g glucose in 1000 ml solution. Depending on the dosage instructions and on the used pack size, up to 57 g glucose (CAPD: 2500 ml stay *stay•safe*) or up to 136 g glucose (APD: 6000 ml *sleep•safe* or *safe•lock*) are supplied to the body with each bag. This should be taken into account in patients with diabetes mellitus.

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 sometimes have a fatal outcome.

Elderly patients
The increased incidence of hernia should be considered in elderly patients 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 medication 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-related adverse reactions. Potassium levels must be monitored particularly during concurrent digitalis therapy.
The concomitant administration of calcium- or vitamin D-containing medicinal products may cause hypercalcaemia.
Use of diuretic agents may help maintain residual renal function, but may also result in water and electrolyte imbalances.
In diabetic patients, the daily dose of insulin or of oral antidiabetic drugs must be adjusted to take account of the increased glucose intake.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of CAPD 2/3/4 in pregnant women. No reproductive toxicity studies have been performed in animals (see section 5.3). CAPD 2/3/4 should not be used during pregnancy unless the clinical condition of the woman requires treatment with CAPD 2/3/4.

Breast-feeding
It is unknown whether CAPD 2/3/4 active substances/metabolites are excreted in human milk. Breast-feeding is not recommended for mothers undergoing peritoneal dialysis.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

CAPD 2/3/4 has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Possible adverse reactions may result from the peritoneal dialysis treatment itself or may be induced by the 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)
- Increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution (common)
- Hyperlipidaemia or deterioration of pre-existing hyperlipidaemia (common)

Cardiac and vascular disorders
- Hypotension (uncommon)
- Tachycardia (uncommon)
- Hypertension (uncommon)

Respiratory, thoracic and mediastinal disorders
- Dyspnoea (uncommon)

Renal and urinary disorders
- Electrolyte disturbances, e.g. hypokalaemia (very common)
- Hypercalcaemia can occur (common) if calcium intake is increased, e.g. through concomitant use of calcium-containing phosphate binders.

General disorders and administration site conditions
- Dizziness (uncommon)
- Oedema (uncommon)
- Disturbances in fluid balance (uncommon) indicated either by a rapid decrease (dehydration) or increase (hyperhydration) in body weight. Severe dehydration might occur when using solutions with higher glucose concentrations.

Potential adverse reactions of the treatment mode
Infections and infestations

- Peritonitis (very common) indicated by a cloudy effluent. Subsequent abdominal pain, fever, and general malaise or, in very rare cases, sepsis may develop. 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 for the white blood cell count.
- Skin infections at the exit site and tunnel infections (very common) indicated by redness, oedema, exudations, crusts and pain at the catheter exit site.
  In case of skin infections at the exit site and of tunnel infections, the attending physician should be consulted as soon as possible.

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
- Dialysis solution inflow and outflow disturbances (common)
- Shoulder pain (common)

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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
https://sideeffects.health.gov.il

4.9 Overdose

No emergency situations in connection with overdose have been reported.
Any excess of dialysis solution infused in the peritoneal cavity can easily be drained into the drainage bag. In case of too frequent exchanges, dehydration and/or electrolyte disturbances can occur, which require 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 hyperhydration or dehydration and electrolyte disturbances.

The most common consequence of an overdosage of CAPD 2/3/4 is dehydration.
Underdosage, interruption 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 dialysis, hypertonic solutions

ATC code: B05D B

CAPD 2/3/4 is a lactate-buffered, glucose-containing electrolyte solution, indicated for intraperitoneal administration for the treatment of end-stage kidny failure of any origin which can be treated by continuous ambulatory peritoneal dialysis (CAPD).

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

The basic principle behind each peritoneal dialysis technique is the use of the peritoneum as a semipermeable 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 dialysis solution is basically the same as that of physiological serum, although it has been adapted (e.g. potassium content) for use in uremic patients to enable renal replacement therapy by means of intraperitoneal substance and fluid exchange. Substances which are normally eliminated in urine, such as urea, creatinine, inorganic phosphate, uric acid, other solutes and water, are removed from the body into the dialysis solution. It should be borne in mind that medication may also be eliminated during dialysis, and that a dose adjustment may thus be necessary.

Individual parameters (such as patient size, body weight, laboratory parameters, residual renal function, ultrafiltration) must be used to determine the dose and combination with the required solutions with differing osmolarity (glucose content) and different potassium, sodium and calcium concentrations. The efficacy of therapy should be regularly monitored on the basis of these parameters.

Peritoneal dialysis solutions with a high glucose concentration (2.3% or 4.25%) are used when the body weight is higher than the desired dry weight. The elimination of fluid from the body increases in relation to the glucose concentration of the peritoneal dialysis solution.

5.2 Pharmacokinetic properties

Uremic retention products, such as urea, creatinine and uric acid, inorganic phosphate, and electrolytes such as sodium, potassium, calcium and magnesium, are removed from the body into the dialysis solution by diffusion and/or convection.
The dialysate glucose used as an osmotic agent in CAPD 2/3/4 is absorbed slowly, decreasing the diffusion gradient between the dialysis solution and the extracellular fluid. Ultrafiltration is highest at the beginning of the dwell time, reaching a peak after about 2 to 3 hours. Later, absorption starts with a progressive loss of ultrafiltration. 60 to 80 % of dialysate glucose is absorbed.
The lactate used as a buffer is almost completely absorbed after a 6-hour dwell time. In patients with a normal hepatic function, the lactate is rapidly metabolised, as demonstrated by the normal values of intermediate metabolites.
Calcium mass transfer depends on the glucose concentration of the dialysis solution, the effluent volume, the serum ionised calcium, and the calcium concentration in the dialysis solution. The higher the glucose concentration, the effluent volume and the serum ionised calcium concentration and the lower the calcium concentration in the dialysis solution, the higher the calcium transfer from the patient to the dialysate.

5.3 Preclinical safety data

No preclinical toxicity studies with CAPD 2/3/4 have been carried out, but clinical studies with comparable solutions for peritoneal dialysis have shown no major risk of toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric acid
Sodium hydroxide
Water for injections

6.2 Incompatibilities

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

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening: The content must be used immediately.

6.4 Special precautions for storage

Store below 25°C. Do not refrigerate. Do not freeze.

6.5 Nature and contents of container

safe•lock:
The *safe•lock* system is provided as a non-PVC bag made of a multi-layered polyolefin-based foil, with tubes inside the bag seams also made of polyolefins, with an injection port made of polyolefin and synthetic rubber and a bag connector made of polycarbonate and silicone components.

stay•safe:
The *stay•safe* system is provided as a double bag system consisting of a non-PVC made of a multi-layered polyolefin-based foil, a tubing system also made of polyolefin, a connector system (DISC, polypropylene), a drainage bag and an overwrap, also made of multi-layered polyolefin film.

sleep•safe:
The *sleep•safe* system is provided as a single bag system consisting of a non-PVC bag made of a multi-layered polyolefin-based foil, a tubing system, a connector, both also made of polyolefin, and an injection port made of polyolefin/synthetic rubber.

Pack sizes:

stay•safe:	*sleep•safe*:	*safe•lock:*
4 bags of 2000 ml each	2 bags of 5000 ml each	2 bags of 5000 ml each
4 bags of 2500 ml each	2 bags of 6000 ml each	2 bags of 6000 ml each

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
***stay•safe* system for continuous ambulatory peritoneal dialysis (CAPD):**

The solution is first warmed up to body temperature. For bags with a volume of up to 3000 ml, an appropriate bag warmer should be used. The heating time for a 2000 ml bag with a starting temperature of 22°C is approx. 120 min. 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 microwave ovens is not recommended due to the risk of local overheating.

1. Check the solution bag (label, expiry date and ensure that the solution is clear) – open the bag overwrap and the packaging of the disinfection cap.
2. Clean your hands with an antimicrobial washing solution.
3. Place the DISC into the organiser (suspend the solution bag from the upper holder of the infusion stand – unroll the "solution bag-DISC" line – place the DISC into the organiser – afterwards place the drainage bag into lower holder of the infusion stand).
4. Place the catheter extension into one of the two inserts of the organiser. Place the new disinfection cap into the other free insert.
5. Disinfect your hands and remove the protective cap of the DISC.
6. Connect the catheter extension to the DISC.
7. Open the clamp of the extension – position **"●"** – outflow procedure starts.
8. After completion of the outflow: Flush - position "●●"–flush with fresh solution that will be drained into the drainage bag (approx. 5 seconds).
9. Inflow – position "○◑●" – connect the solution bag to the catheter.
10. Safety measure – position "●●●●" – automated closing of the catheter extension by inserting the PIN.
11. Disconnection - remove the protective cap from the new disinfection cap and screw it onto the old one. Unscrew the catheter extension from the DISC and screw the catheter extension onto the new disinfection cap.
12. Close the DISC with the open end of the protective cap (which has remained in the right insert of the organiser).
13. Check the drained dialysate for clarity and quantity and, if the effluent is clear, discard it.

sleep•safe system (for the setup of the *sleep•safe* system, please refer to its operating instructions):

1. Preparation of the solution
   - Check the solution bag (label, expiry date, clearity of the solution, bag and overwrap not damaged).
   - Place the bag on a solid surface.
   - Open the overwrap of the solution bag.
   - Wash your hands with an antimicrobial washing lotion.
   - Check whether the solutive is clear and that the bag is not leaking.
2. Unroll the tubing of the solution bag.
3. Remove the protection cap.
4. Insert the connector into the free *sleep•safe* tray port.
5. The bag is now ready for use with the *sleep•safe* set.

safe•lock system for automated peritoneal dialysis (APD)
(for the setup of the *safe•lock* system, please refer to its operating instructions):

1. Preparation of the solution
   - Check the solution bag (label, expiry date, clarity of the solution, bag and overwrap not damaged).
   - Place the bag on a solid surface.
   - Open the overwrap of the bag.
   - Wash your hands with an antimicrobial washing lotion.
   - Check whether the solution is clear and that the bag is leak proof.
   - Place the bag on the heater plate or hang it on a hook of the infusion stand of the cycler.
2. Remove the protective cap of the connector from the connecting line of the tubing set.

3. Remove the protective cap from the bag connector and connect the line of the tubing set.
4. Break the inner lock by bending the line and the PIN by more than 90° to both sides.
5. The bag is now ready for use.

A separate injection can be performed through the injection port.

See also section 4.2.

Handling

Plastic containers may occasionally be damaged during transport or storage. This can result in a contamination, leading to proliferation 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 a cloudy content should never be used! In case of doubt, the attending physician should decide on the use of the solution.

Only use the peritoneal dialysis solution if container and seal are undamaged.

The overwrap should only be removed before administration.

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

Addition of medication to the peritoneal dialysis solution:

The addition of medication to the peritoneal dialysis solution is generally not recommended because of the risk of contamination and of incompatibility between the peritoneal dialysis solution and the medication. When adding drugs, use an aseptic technique, mix thoroughly and after checking for the absence of any turbidity, which may occur due to incompatibilities, the peritoneal dialysis solution must be used immediately.

7. MANUFACTURER

Fresenius Medical Care Deutschland GmbH,
Else-Kroner-Strasse 1, D-61352 Bad Homburg v.d.H., Germany

8. LICENSE HOLDER

Fresenius Medical Care Israel P.B. Ltd.,
4 HaSheizaf St., 4366411 Raanana, Israel

9. REGISTRATION NUMBERS

CAPD 2 Peritoneal Dialysis Solution	107-95-26735-00
CAPD 3 Peritoneal Dialysis Solution	107-96-26734-00
CAPD 4 Peritoneal Dialysis Solution	107-97-26736-00

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