PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

CAPD 17 Solution for Peritoneal Dialysis
CAPD 18 Solution for Peritoneal Dialysis
CAPD 19 Solution for Peritoneal Dialysis

Composition:
Each liter of solution contains:

	CAPD 17	CAPD 18	CAPD 19
Calcium chloride dihydrate	0.1838 g	0.1838 g	0.1838 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) (Fructose, up to)	16.5 g (15.0 g) (0.75 g)	46.75 g (42.5 g) (2.1 g)	25 g (22.73 g) (1.1 g)
Ca^{2+}	1.25 mmol/l	1.25 mmol/l	1.25 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^{-}	102.5 mmol/l	102.5 mmol/l	102.5 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
Theoretical osmolarity:	356 mOsm/l	509 mOsm/l	399 mOsm/l

pH ≈ 5.5

Inactive ingredients and allergens – see section 6 "Further information" and section 2 "Before using the medicine".

Read all of this leaflet carefully before you start using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor, pharmacist or nurse.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?
For use in patients suffering from end-stage chronic renal failure who are being treated with peritoneal dialysis.

Therapeutic group: Peritoneal dialytics, hypertonic solutions

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:
- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine.
- The level of potassium in your blood is very low.
- The level of calcium in your blood is very low.
- You suffer from disorders of lactate metabolism (lactic acidosis).
- You have fructose metabolism disorders (hereditary fructose intolerance). A non-recognized hereditary fructose intolerance must be excluded prior to administration to babies and infants.
- The volume of your body fluids is too low (for CAPD 18 and 19 only).
- You have low blood pressure (for CAPD 18 and 19 only).

Peritoneal dialysis treatment must not be started if you suffer from:
- alterations in the abdominal region such as:
  - Injuries, or after surgery
  - History of abdominal operations with fibrous adhesions
  - Severe burns
  - Bowel perforation
  - Extensive inflammatory skin reactions (dermatitis)
  - Inflammation of the peritoneum
  - External or internal abdominal fistula
  - Non-healing, weeping wounds
  - Umbilical, inguinal, diaphragmatic or other abdominal hernias
  - Tumours in the abdomen or bowel
- inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis)
- intestinal obstruction
- lung disease, particularly pneumonia
- blood poisoning caused by bacteria (sepsis)
- extremely high levels of fat in the blood
- poisoning due to urine products in the blood which cannot be treated by blood cleaning
- severe malnutrition and loss of weight, particularly if adequate intake of food containing proteins is not possible
- physical or mental incapability to undergo peritoneal dialysis in accordance with the doctor's instructions.

If any of these disturbances develop during dialysis treatment, refer to the doctor so that he can make a decision regarding further treatment.

Special warnings regarding use of the medicine:
- **Before using CAPD 17/18/19, inform the doctor immediately if:**
  - You have a **severe loss of electrolytes (salts)** due to vomiting and/or diarrhoea
  - You have an **overactive parathyroid** or **a low calcium level in the blood**. It may be necessary to take additional calcium-containing phosphate binders and/or vitamin D.
    If this is not possible a peritoneal dialysis solution with a higher calcium concentration should be used.
  - You have an **inflammation of the peritoneum**, recognisable by a cloudy dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning.
    Show the bag containing the drained dialysate to a doctor.
  - You have **severe abdominal pain, abdominal distension or vomiting.** This can be a sign of encapsulating peritoneal sclerosis, a complication of the peritoneal dialysis therapy that can be fatal.
- Peritoneal dialysis can lead to a **loss of proteins** and **water-soluble vitamins**. An adequate diet or nutritional supplements are recommended in order to avoid deficiency states.
- The high glucose concentration dialysis solutions (CAPD 18 and 19) should be used cautiously, to avoid dehydration and to limit glucose intake. CAPD solution is not biocompatible.
- Elderly patients are at increased risk of a hernia.

Tests and follow-up:
The doctor will regularly monitor your:
- Electrolyte (salts) balance – sodium, potassium, calcium, magnesium, phosphate, acid base balance
- Blood proteins
- Serum creatinine and urea
- Blood sugar
- Parathyroid gland hormones and other indicators of bone metabolism
- Blood cell counts
- Kidney function
- Body weight and nutritional status

Drug interactions
If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Because peritoneal dialysis may influence the effects of medicines, the doctor may need to change their dosage, especially those of:
- **Medicines for heart failure**, such as digitoxin. The doctor will check the level of potassium in your blood and, if necessary, will take appropriate measures.
- **Medicines that influence calcium levels**, such as those containing calcium or vitamin D.
- **Medicines that increase the excretion of urine,** such as diuretics.
- **Medicines** taken by mouth **that lower blood sugar levels** or insulin. Your blood sugar levels should be measured regularly (see section "Important information about some of the ingredients of the medicine").

Pregnancy and breast-feeding:
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the doctor for advice before taking this medicine.
There are no adequate data from the use of CAPD 17/18/19 in pregnant women or during lactation period.
If you are pregnant, you should not use CAPD 17/18/19 unless the doctor considers this absolutely necessary.
It is unknown whether CAPD 17/18/19 substances/metabolites are excreted in human milk. Breast-feeding is not recommended for mothers on peritoneal dialysis.

Driving and use of machines:
CAPD 17/18/19 has no or negligible influence on the ability to drive or use machines.

Important information about some of the ingredients of the medicine:
- **CAPD 17** contains 15 g glucose in 1000 ml solution. Depending on the dosage instructions and the pack size used up to 45 g glucose (CAPD, 3000 ml stay•safe) or up to 75 g glucose (APD, 5000 ml sleep•safe) are supplied to the body with each bag.
- **CAPD 18** contains 42.5 g glucose in 1000 ml solution. Depending on the dosage instructions and the pack size used up to 127.5 g glucose (CAPD, 3000 ml stay•safe) or up to 212.5 g glucose (APD, 5000 ml sleep•safe) are supplied to the body with each bag.
- **CAPD 19** contains 22.73 g glucose in 1000 ml solution. Depending on the dosage instructions and the pack size used up to 68.2 g glucose (CAPD, 3000 ml stay•safe) or up to 113.65 g glucose (APD, 5000 ml sleep•safe) are supplied to the body with each bag.

This should be taken into account in patients with diabetes mellitus.
Due to the high glucose concentration CAPD 18 and CAPD 19 should be used cautiously and under monitoring by a doctor.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are not sure about the dosage and treatment regimen of the preparation.
The doctor will determine the method, duration and frequency of use and the required volume of solution and dwell time in the peritoneal cavity.
If tension occurs in the abdominal region the doctor may reduce the volume.

The dosage and the method of treatment will be determined by the doctor only. The usual dosage is:

<u>Continuous ambulatory peritoneal dialysis (CAPD)</u>:
- **Adults:** 2000-3000 ml solution four times daily depending on body weight and kidney function.
  After 2-10 hours dwell time the solution is drained off.
- **Children:** The doctor will determine the volume of the dialysis solution required depending on the tolerance, age and body surface area of the child.
  The recommended initial dose is 600-800 ml/m² (up to 1000 ml/m² overnight) body surface area four times daily.

<u>Automatic peritoneal dialysis (APD)</u>:
Bag exchange is controlled automatically by the machine over-night. For this type of dialysis, the CAPD sleep-safe system is used.
- **Adults:** 2000 ml (maximum 3000 ml) per exchange with 3-10 exchanges overnight and time on the cycler 8 to 10 hours, and at daytime one or two exchanges.
- **Children:** The volume per exchange should be 800-1000 ml/m² (up to 1400 ml/m²) body surface area with 5-10 exchanges overnight.

Do not exceed the recommended dose.

Use CAPD 17/CAPD 18/ CAPD 19 in the **peritoneal cavity only**.
Use CAPD 17/CAPD 18/ CAPD 19 only if the solution is clear and the bag is undamaged.

Handling instructions:

<u>Stay-safe system for continuous ambulatory peritoneal dialysis (CAPD)</u>
The solution bag is first warmed to body temperature. For bags with a volume up to 3000 ml this should be done by using an appropriate bag warmer. The heating time depends on the bag volume and the used bag warmer (for a 2000 ml bag with a starting temperature of 22 °C usually 120 min). More detailed information can be obtained from the operating instructions of the bag warmer.
A microwave oven must not be used to warm the solution due to the risk of local overheating.
After warming the solution, you can start with the exchange of the bags.
1. Check the solution bag (label, expiry date, clearness of the solution, bag and overwrap not damaged). ➧ Open the overwrap of the bag and the packaging of the disinfection cap/closure cap.
2. Wash your hands with an antimicrobial washing solution.
3. Place the DISC into the organizer (suspend solution bag from the upper hole of the infusion pole ➧ unroll the "solution bag-DISC" line ➧ place the DISC into the organizer ➧ place drainage bag into lower holder of the infusion pole).
4. Place catheter extension into one of the two inserts of the organizer. ➧ Place the new disinfection cap/closure cap into the other free insert.
5. Disinfect your hands and remove the protection cap of the DISC.
6. Connect catheter extension to the DISC.
7. Open the clamp on extension ➧ position "●" ➧ outflow procedure starts.
8. After completion of the outflow: Flush ➧ position "●●" ➧ flush fresh dialysate into the drainage bag (approximately 5 seconds).
9. Inflow ➧ position "○◑●" ➧ connect the solution bag with the catheter.
10. Security step ➧ position "●●●●" ➧ automated closing of the catheter extension with the PIN.
11. Disconnection ➧ remove the protection cap from the new disinfection cap/closure cap and screw it onto the old one ➧ unscrew catheter extension from the DISC and screw it onto the new disinfection cap/closure cap.
12. Close the DISC with the open end of the protection cap (which has remained in the other insert of the organizer).
13. Check the drained dialysate for clarity and weight and if the effluent is clear discard it.

<u>Sleep-safe system for automatic peritoneal dialysis (APD)</u>
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, clearness 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 not leaking.
2. Unroll the tubing of the bag.
3. Remove the protection cap.
4. Insert connector into free tray port.
5. The bag is now ready for use with the sleep-safe set.

Each bag should be used only once and any unused solution remaining must be discarded.
After appropriate training, CAPD 17/CAPD 18/CAPD 19 can be used independently at home. Ensure that you follow all the procedures you learnt during training and maintain hygienic conditions when exchanging bags.
Always check the drained dialysate for cloudiness. See section 2.

If you have accidentally taken a higher dose
If you allowed too much solution to flow into the peritoneal cavity, the excess can be drained off. If you used too many bags, contact the doctor as this can result in fluid and/or electrolyte imbalances.

If a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to use this medicine
Try to attain the volume of dialysate prescribed for each 24-hour period in order to avoid the risk of possibly life-threatening consequences. You should check with the doctor if you are not sure.

Discontinued use of the medicine, use of too low a dosage or disruption of the treatment may lead to life-threatening situations, such as excess fluid in the body, with peripheral edema and heart failure and/or other symptoms of uremia (presence of excess amounts of urine products in the blood). **Refer to a doctor immediately.**
Adhere to the treatment regimen recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, ask the doctor, pharmacist or nurse.

4. SIDE EFFECTS:
As with any medicine, use of CAPD 17/18/19 may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The following side effects may occur as a result of the peritoneal dialysis treatment in general:

Very common side effects (may affect more than 1 in 10 people treated):
- Inflammation of the peritoneum with signs of cloudiness of the drained dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning.
  Please show the bag containing the drained dialysate to the doctor.
- Inflammation of the skin at the catheter exit site or along the length of the catheter, recognizable by redness, swelling, pain, weeping or crusts.
- Hernia of the abdominal wall.

Contact a doctor immediately if you notice any of these side effects.

Other side effects of the treatment are:
Common side effects (may affect 1-10 in 100 people treated):
- Problems with inflow or outflow of the dialysate
- Sensation of stretching or fullness of the abdomen
- Shoulder pain

Uncommon side effects (may affect 1-10 in 1000 people treated):
- Diarrhoea
- Constipation

Side effects of unknown frequency (frequency cannot be estimated from available data):
- Breathing difficulties due to elevation of the diaphragm
- Encapsulating peritoneal sclerosis, possible symptoms may be abdominal pain, abdominal distension or vomiting

The following side effects may occur when CAPD 17/18/19 is used:
Very common side effects (may affect more than 1 in 10 people treated):
- Potassium deficiency

Common side effects (may affect 1-10 in 100 people treated):
- High blood sugar levels
- High blood fat levels
- Weight gain

Uncommon side effects (may affect 1-10 in 1000 people treated):
- Calcium deficiency
- Body fluid levels too low, which can be recognised by rapid weight loss
- Dizziness
- Low blood pressure
- Rapid pulse
- Body fluid levels too high which can be recognised by rapid weight gain
- Water in the tissues and lungs
- High blood pressure
- Breathing difficulties

Side effects of unknown frequency (frequency cannot be estimated from available data):
- Overactive parathyroid with potential disturbances of the bone metabolism

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult a doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" located on the Ministry of Health homepage (<u>www.health.gov.il</u>) that directs you to the online form for reporting side effects, or by entering the link: <u>https://sideeffects.health.gov.il</u>

5. HOW SHOULD THE MEDICINE BE STORED?
- **Avoid poisoning!** This medicine and any other medicine should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the bag and carton. The expiry date refers to the last day of that month.
- Store the solution below 25 °C. Do not refrigerate. Do not freeze.
- The solution must be used immediately after opening.

6. FURTHER INFORMATION:
In addition to the active ingredients, the medicine also contains:
Water for Injections, Hydrochloric Acid, Sodium Hydroxide.

What the medicine looks like and the contents of the package:
The solution is clear and colourless to slightly yellow.

Package sizes and types:
<u>Stay-safe</u>:
4 bags of 2000 ml,
4 bags of 2500 ml,
4 bags of 3000 ml.
<u>Sleep-safe</u>:
2 bags of 5000 ml.
** Not all package sizes may be marketed.

Registration Holder and address: Fresenius Medical Care Israel P.B. Ltd., 4 Hasheizaf St., 4366411 Raanana, Israel.

Manufacturer and address: Fresenius Medical Care Deutschland GmbH, Else-Kroner-Strasse 1, 61352 Bad Homburg, v.d.H., Germany.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:
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