

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

CAPD 2 peritoneal dialysis solution

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Solution for peritoneal dialysis

Composition:
Each liter of solution 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) (Fructose, up to)	16.5 g (15.0 g) (0.75 g)	46.75 g (42.5 g) (2.1 g)	25.0 g (22.73 g) (1.1 g)
Ca²⁺	1.75 mmol/l	1.75 mmol/l	1.75 mmol/l
Na⁺	134 mmol/l	134 mmol/l	134 mmol/l
Mg²⁺	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
Theoretical osmolality	358 mOsm/l	511 mOsm/l	401 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 this medicine. This leaflet contains concise information about the medicine. If you have any 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 USED FOR?
CAPD solutions are intended for the treatment of patients who suffer from end-stage chronic renal failure and 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 high**
- you suffer from **disorders of lactate metabolism**
- you have **fructose metabolism disorders** (hereditary fructose intolerance)
- the **volume of your body fluids is too low** (for CAPD 3 only)
- you have **low blood pressure** (for CAPD 3 only)

Peritoneal dialysis treatment must not be started if you have

- alterations in the abdominal region such as:
 - injuries, or after surgery
 - severe burns
 - large, inflammatory skin reactions
 - inflammation of the peritoneum
 - non-healing, weeping wounds
 - umbilical, inguinal or diaphragmatic hernias
 - tumours in the abdomen or bowel
- inflammatory bowel diseases
- intestinal obstruction
- lung diseases, particularly pneumonia
- blood poisoning caused by bacteria
- extremely high levels of fat in the blood
- poisoning due to urine products in the blood, which can no longer be treated by blood cleaning
- severe malnutrition and weight loss, particularly if adequate intake of food containing proteins is not possible.

Special warnings regarding use of the medicine
Before using CAPD inform your doctor immediately:

- if you have a **severe loss of electrolytes (salts)** due to vomiting and/or diarrhoea.
- if you have an **inflammation of the peritoneum**, recognisable by a cloudy dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning.

Please show the bag containing the drained dialysate to your doctor.

- if 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 state.

Tests and follow-up:
Your doctor will check your electrolyte (salt) balance, 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, your doctor may need to change their dosages, especially those of:

- **medicines for heart failure**, such as digitoxin.
 - your 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 level should be measured regularly.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. There are no adequate data from the use of CAPD 2/3/4 in pregnant women or during lactation period.

If you are pregnant, you should not use CAPD 2/3/4 unless your doctor considers this absolutely necessary. It is unknown whether CAPD 2/3/4 substances/metabolites are excreted in human milk. Breast-feeding is not recommended for mothers undergoing peritoneal dialysis.

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

Important information about some of the ingredients of the medicine:
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•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.

Due to the high glucose concentration, CAPD 3 and CAPD 4 should be used cautiously and under monitoring by your doctor. CAPD solution is not biocompatible.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use this medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and treatment regimen of the medicine. Your 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, your doctor may reduce the volume.

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

The usual dosage is:
Continuous ambulatory peritoneal dialysis (CAPD):

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

Automated peritoneal dialysis (APD):
Bag exchange is controlled automatically by the machine overnight. For this type of dialysis, the CAPD sleep•safe system or the safe•lock system is used.

- **Adults:** The usual prescription is 2000 ml (maximum 3000 ml) per exchange, with 3-10 exchanges overnight and time on the cyclor of 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) of body surface area, with 5-10 exchanges overnight.

Do not exceed the recommended dose.
Use CAPD 2/3/4 in the peritoneal cavity only.
Use CAPD 2/3/4 only if the solution is clear and the bag is undamaged.
Handling instructions
sleep•safe system for continuous ambulatory peritoneal dialysis (CAPD):

The solution bag is first warmed to body temperature. This should be done by using an appropriate bag warmer. The heating time for a 2000 ml bag with a starting temperature of 22°C is approximately 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.
2. Clean your hands with an antimicrobial washing solution.
3. Place the DISC into the organiser (suspend the solution bag from the upper hole of the infusion pole ⇒ unroll the "solution bag-DISC" line ⇒ place the DISC into the organiser ⇒ place the drainage bag into the lower holder of the infusion pole).
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 fresh dialysate to the drainage bag (approx. 5 seconds).
9. Inflow ⇒ position "○●" ⇒ connect the solution bag with the catheter.
10. Security step ⇒ position "●●●●" ⇒ close the catheter extension by inserting the PIN.
11. Disconnection ⇒ remove the protection 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 used disinfection cap (which has remained in the right hole of the organiser).
13. Check the drained dialysate for clarity and weight and, if the effluent is clear, discard it.

sleep•safe system for automated peritoneal dialysis (APD):
During automated peritoneal dialysis (APD), the solution is warmed automatically in the machine.

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. ⇒ 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 solution bag.
3. Remove the protective 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):
During automated peritoneal dialysis (APD), the solution is warmed automatically in the machine.

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. ⇒ Place the bag on the heater plate or hang it on a hook of the infusion stand of the cyclor.
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.

Each CAPD 2/3/4 bag should be used only once and any unused solution must be discarded.

After appropriate training, CAPD 2/3/4 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 accidentally taken a higher dose
If you allow too much solution to flow into the peritoneal cavity, the excess can be drained off. If you use too many bags, please contact your doctor as this can result in fluid and/or electrolyte imbalances.
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 potential life-threatening consequences. You should check with your doctor if you are not sure.
Adhere to the treatment regimen recommended by the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. SIDE EFFECTS
Like all medicines, use of CAPD 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** (affect more than one in ten users):
 - inflammation of the peritoneum with signs of cloudiness of the drained dialysate, abdominal pain, fever, feeling unwell and in very rare cases blood poisoning.
 - Please show the bag containing the drained dialysate to your doctor.
 - inflammation of the skin at the catheter exit site or along the length of the catheter, recognisable 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 (affect 1-10 in 100 users):

- problems with the inflow or outflow of the dialysate
- sensation of stretching or fullness of the abdomen
- shoulder pain

uncommon side effects (affect 1-10 in 1,000 users):

- 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 2/3/4 is used:

- **very common side effects** (affect more than one in ten users):
 - potassium deficiency
- **common side effects** (affect 1-10 in 100 users):
 - high blood sugar levels
 - high blood fat levels
 - weight gain
 - calcium excess if the calcium intake is too high
- **uncommon side effects** (affect 1-10 in 1,000 users):
 - 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.

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.

Reporting of side effects
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 (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

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 this 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 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 injection, hydrochloric acid, sodium hydroxide.

What the medicine looks like and contents of the package:
The solution is clear and colourless to slightly yellow.
CAPD 2/3/4 is available in cartons with the following application systems and pack sizes:

<i>stay•safe:</i>	<i>sleep•safe:</i>	<i>safe•lock:</i>
4 × 2000 ml bags	2 × 5000 ml bags	2 × 5000 ml bags
4 × 2500 ml bags	2 × 6000 ml bags	2 × 6000 ml bags

Not all pack 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, D-61352 Bad Homburg v.d.H., Germany
Revised in August 2022 according to MOH guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
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
CAPD 2,3,4 SOL PL SH 120522