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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

The active ingredients and their quantity/concentration:
Each liter of solution contains:

	CAPD 17	CAPD 18	CAPD 19
Sodium chloride	5.786 g	5.786 g	5.786 g
Sodium lactate = Sodium lactate solution 50%	3.925 g = 7.85 g	3.925 g = 7.85 g	3.925 g = 7.85 g
Calcium chloride	0.1838 g	0.1838 g	0.1838 g
Magnesium chloride	0.1017 g	0.1017 g	0.1017 g
Glucose (as monohydrate)	16.5 g	46.75 g	25 g

For the list of inactive ingredients, please see section 6.
Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor 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 the purpose of use is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

For use in patients suffering from chronic renal failure, who are being treated with peritoneal dialysis.

Therapeutic group: Solution for peritoneal dialysis.

2. BEFORE USING THE MEDICINE:

☒ Do no use the medicine if:
- You are sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine.
- You have very low blood potassium levels.
- You have very low blood calcium levels.
- You are suffering from lactate metabolism disturbances (lactic acidosis).
- You have fructose metabolism disturbances (hereditary fructose intolerance). Rule out unrecognized hereditary fructose intolerance before starting treatment in infants and toddlers.
- The volume of the fluids in your body is too low (for CAPD 18 and 19 only).
- You have low blood pressure (for CAPD 18 and 19 only).

☒ Do not start peritoneal dialysis treatment in the following circumstances:
- If you have changes in the abdominal area, such as:
  - Injuries, or after surgery
  - History of abdominal surgeries with fibrous adhesions
  - Severe burns
  - Intra-abdominal 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 hernia
  - Intra-abdominal tumor
  - Ulcers
- If you are suffering from inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis),
- If you are suffering from bowel obstruction
- If you are suffering from lung disease, particularly pneumonia
- If you are suffering from blood poisoning caused by bacteria (sepsis)
- If you are suffering from very high blood fat levels
- If you are suffering from a rare poisoning as a result of urine products in the blood (uremia), which can not be treated by blood cleaning (peritoneal dialysis).
- If you are suffering from severe malnutrition which causes loss of muscle mass and weight loss, especially if you can not consume sufficient amount of food containing proteins.
- In patients who can not physically or mentally 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:
- **Inform the doctor immediately if:**
  - You have **a severe loss of electrolytes (salts)** due to vomiting and/or diarrhea (a temporary change to a peritoneal dialysis solution containing potassium may be necessary).
  - You have **hyperparathyroidism** 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**, which can be identified by a cloudy or reduced volume of fluid remaining at the end of the dialysis, abdominal pain, fever, malaise or very rarely, blood poisoning (sepsis). Show the doctor the bag containing the drained dialysis fluid.
- Blood cleaning can lead to **a loss of proteins and water-soluble vitamins**. An appropriate diet or nutritional supplements are recommended to prevent a state of deficiency.
- The high glucose concentration dialysis solutions (CAPD 18 and 19) should be used cautiously – to avoid dehydration and to limit glucose intake.
- Elderly patients are at increased risk of a hernia.

! Tests and follow-up:
The doctor will regularly monitor:
- Your body weight and nutritional status
- Your electrolyte (salts) balance - sodium, potassium, calcium, magnesium, phosphate, acid base balance
- Blood proteins
- Blood creatinine and urea
- Blood sugar
- Parathyroid gland hormones and other indicators of bone metabolism
- Blood count
- Kidney function

! Important information about some of the ingredients of the medicine:
- The **CAPD 17** solution contains 15 gr glucose and up to 0.75 gr fructose per 1000 ml solution. In other words, up to 30 gr glucose are supplied to the body in each 2000 ml bag.
- The **CAPD 18** solution contains 42.5 gr glucose and up to 2.1 gr fructose per 1000 ml solution. In other words, up to 85 gr glucose are supplied to the body in each 2000 ml bag.
- The **CAPD 19** solution contains 22.73 gr glucose and up to 1.1 gr fructose per 1000 ml solution. In other words, up to 45 gr glucose are supplied to the body in each 2000 ml bag.

In diabetic patients, the amount of glucose absorbed by the body should be taken into consideration and the dosage of diabetic medicines adjusted accordingly (see further information about diabetes medicines in the next section).

! If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking medicines from the following groups, since the use of the peritoneal dialysis solution may affect the effectiveness of other medicines and a dosage adjustment may be necessary:
- **Medicines for heart failure**, such as digoxin. The doctor will check the level of potassium in your blood and will take appropriate measures as necessary
- **Medicines that influence calcium levels**, such as those containing calcium or vitamin D
- **Diuretics**, such as hydrochlorothiazide
- **Diabetes medicines** taken by mouth, or insulin. Blood sugar levels should be measured regularly. In diabetic patients, the insulin dose or the dosage of oral diabetes medicines should be adjusted in accordance with the glucose absorption in dialysis patients (see section "Important information about some of the ingredients of the medicine")

! Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, consult the doctor or pharmacist before using medicines.
There is not sufficient information about use of the preparation during pregnancy or breastfeeding.

! Driving and use of machines:
When using the medicine in accordance to the instructions, CAPD does not affect your ability to drive or operate machines.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
- The doctor will decide on the technique, duration and frequency of use, required volume of solution and retention time in the abdominal cavity.
- **After appropriate training, you can perform the dialysis on your own at home. Strictly follow the instructions given during training.**
- Be sure to maintain hygienic conditions when switching bags to reduce the risk of infections.
- For use **in the peritoneum cavity only** (intraperitoneal use only).
- **Do not** use the peritoneal dialysis solution for intravenous infusion.
- Use the CAPD solution only if the solution is clear and the bag is not damaged.
- If tension forms in the abdominal region, reduce the volume.
- Use each bag only once, and discard the residual solution.
- Always check whether the drained dialysis solution is cloudy. See section 2 "Special warnings regarding use of the medicine".

The dosage and the treatment regimen will be determined by the doctor only. The usual dosage is generally:

Continuous ambulatory peritoneal dialysis (CAPD):
- **Adults and elderly:** 2000-3000 ml solution, 4 times daily, depending on body weight and kidney function. The appropriate dose is inserted into the abdominal cavity, over 5-20 minutes, via a catheter.
  After a 2-10-hour retention time, according to the doctor's instructions, the solution should be drained.
- **Children and adolescents up to 18 years of age:** The doctor will determine the volume of the dialysis solution required depending on the age, height and body weight of the child. The recommended dosage is 30–40 ml/kg body weight.

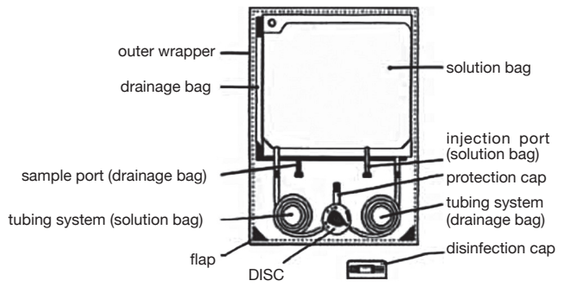
Automatic peritoneal dialysis (APD):
Bag exchange during the night is controlled automatically by the machine. For this, use the sleep-safe system.

Do not exceed the recommended dose.

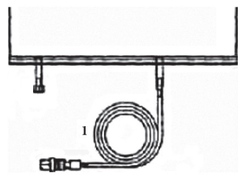
Instructions for use:

Stay-safe system for continuous ambulatory peritoneal dialysis (CAPD) – see diagram
First, warm the solution to body temperature. Do this by using an appropriate heater tray. The heating time for a 2000 ml bag with a starting temperature of 22°C is approximately 120 min. More detailed information can be found in the operating instructions of the bag warmer.

Do not use a microwave to warm the solution since there is a risk of localized overheating.
After warming the solution, you can start with the exchange of the bags.
1. Check the solution bag (label, expiry date, clarity of the solution, and that the bag and wrapper are not damaged). Take off the outer wrapper and package of the disinfection cap.
2. Wash your hands with an antimicrobial soap.
3. Place the DISC into the organizer (suspend solution bag from the upper hole of the infusion pole – unroll the line "solution bag-DISC" – place the DISC into the organizer – afterwards place drainage bag into lower holder of the infusion pole).
4. Place catheter adapter into the organizer.
5. Disinfect your hands and remove the protection cap of the DISC.
6. Connect catheter adapter to the DISC.
7. Open the catheter clamp - position "●" indicates that the draining procedure is on.
8. Flush position "●●" indicates that the flush of fresh dialysate to the drainage bag is being executed (approximately 5 seconds).
9. Inflow position "○◑●●" indicates that the solution bag and the catheter are connected.
10. Security switch position "●●●●" - automatically closes the catheter adapter with the PIN.
11. Disconnection (remove the catheter adapter from the DISC opening) – screw the catheter adapter to the new disinfection cap.
12. Close the DISC. Close the DISC with the open end of the protection cap of the used disinfection cap (which is placed in the right hole of the organizer).
13. Check the drained dialysate and discard it.



Sleep-safe system for automatic peritoneal dialysis (APD) – see diagram
See the sleep-safe instructions for use.
During automatic peritoneal dialysis the solution is warmed automatically in the machine.
1. Preparation of the solution
   - Check the solution bag (label, expiry date, clarity of the solution and that the bag and wrapper are not damaged).
   - Place the bag on a steady surface.
   - Take off the outer wrapper of the bag.
   - Wash your hands with an antimicrobial soap.
   - Make sure that the solution is clear and that the bag is not leaking.
2. Unroll the tubing of the bag (1).
3. Remove the protective cap.
4. Insert connector into the free sleep-safe tray port.
5. The bag is now ready for use with the sleep-safe set.



If you accidentally used a higher dosage
If you allowed too much solution to flow into the abdominal cavity, the excess can be drained. If you used too many bags, contact the doctor as this can result in an electrolyte and/or fluid imbalance. In case of overdose, dehydration is the most common effect.

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 at the required time, to avoid risk of potential life-threatening effects, refer to a doctor.

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 each time you take medicine. Wear glasses if you need them.

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

4. SIDE EFFECTS:

As with any medicine, use of CAPD solution may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Side effects relating to the dialysis technique:

Refer to a doctor as soon as possible upon onset of any of the very common side effects:
- Inflammation of the peritoneum with signs of cloudiness of the drained dialysis fluid, abdominal pain, fever, malaise or very rarely, blood poisoning (sepsis). Show the bag containing the drained dialysis solution to the doctor.
- Inflammation of the skin at the catheter exit site or along the length of the catheter, which can be identified by redness, swelling, pain, discharge or crusts.
- Abdominal wall hernia.

Additional side effects:

Common side effects:
- Problems with flow or drainage of the dialysis fluid
- Sensation of stretching or fullness of the abdomen
- Shoulder pain

Uncommon side effects:
- Diarrhea
- Constipation

Side effects of unknown frequency:
- Breathing difficulties due to elevation of the diaphragm

Effects related to the solution:

Very common side effects:
- Electrolyte disturbances such as: potassium deficiency

Common side effects:
- High blood sugar levels
- High blood fat levels (hyperlipidemia) or worsening of hyperlipidemia
- Weight gain

Uncommon side effects:
- Calcium deficiency
- Too low body fluid levels (dehydration), which can be identified by rapid weight loss. Severe dehydration may occur when solutions with a higher glucose concentration are used
- Dizziness
- Low blood pressure
- Rapid pulse
- Too high body fluid levels (fluid retention), which can be identified by rapid weight gain
- Water in the tissues and lungs (edema)
- High blood pressure
- Breathing difficulties

Side effects of unknown frequency:
- Secondary hyperparathyroidism 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 with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found 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 the medicine after the expiry date (exp. date) that appears on the bag and package. The expiry date refers to the last day of that month.
- Store the solution below 25°C. Do not refrigerate. Do not freeze.
- Use the solution immediately after opening.

6. FURTHER INFORMATION:

In addition to the active ingredients, the medicine also contains:
Water for injections, Hydrochloric Acid, Sodium Hydroxide
The solution contains sugar (glucose and fructose) – see information regarding the sugar content in section 2: "Important information about some of the ingredients of the medicine"

What the medicine looks like and the contents of the package:
A bag containing a clear and colorless to slightly yellowish solution.
Package sizes and types:

Stay-safe:
4 bags of 2000 ml,
4 bags of 2500 ml,
4 bags of 3000 ml.

Sleep-safe:
2 bags of 5000 ml.
** Not all package sizes may be marketed.

Registration Holder and address: NEPHROMED Ltd., 7 Carlebach Street, Tel Aviv.

Manufacturer and address: Fresenius Medical Care Deutschland Ltd., Bad Homburg, Germany

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
CAPD 17: 134 78 31163
CAPD 18: 134 79 31164
CAPD 19: 134 80 31165