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PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

Dispensing of this medicine requires physician's prescription

CAPD 2, 3, 4, Peritoneal Dialysis Solution

Composition per liter:

| CAPD 2: | CAPD 3: | CAPD 4: |
|----------------------------|----------------------------|----------------------------|
| Sodium chloride 5.786g, | Sodium chloride 5.786g, | Sodium chloride 5.786g, |
| Sodium lactate 3.925g, | Sodium lactate 3.925g, | Sodium lactate 3.925g, |
| Calcium chloride 0.2573g, | Calcium chloride 0.2573g, | Calcium chloride 0.2573g, |
| Glucose anhydrous 15.0g, | Glucose anhydrous 42.5g | Glucose anhydrous 22.73g |
| Magnesium chloride 0.1017g | Magnesium chloride 0.1017g | Magnesium chloride 0.1017g |

Read this package insert carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or nurse.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that the purpose is similar.

Therapeutic activity:

CAPD solutions are intended for treatment of patients who suffer from chronic renal failure and are being treated with peritoneal dialysis.

When should the preparation not be used?

- Do not use CAPD 2, CAPD 3, CAPD 4 if you suffer from severe hypokalemia or severe hypercalcemia, lactic acidosis, localised peritonitis, intra-abdominal perforations, severe abdominal burns, widespread inflammation (dermatitis) of the abdominal skin in the catheter area, if you suffer from an internal or external abdominal fistula, if you suffer from intra-abdominal tumors, abdominal injuries, if you have recently undergone abdominal surgery, if you suffer from umbilical, inguinal or other hernias, lung disease (especially pneumonia), if you suffer from loss of muscle mass (cachexia) and weight loss particularly if adequate intake of protein supplements is not possible, from extreme hyper-lipidemia, from adhesions as a result of previous surgery, inflammatory bowel disease (Crohn's disease, ulcerative colitis, diverticulitis), ileus, sepsis, in rare cases of uremia which cannot be treated by peritoneal dialysis, if you suffer from fructose intolerance.
- Do not use in patients who are physically or mentally incapable of performing peritoneal dialysis according to the instructions.
- Do not use CAPD 3 if you suffer from hypovolemia, low blood pressure.

Do not use this preparation without consulting a physician before starting treatment:

- If you are in an advanced stage of pregnancy.
- if you are diabetic.
- If you suffer from severe loss of electrolytes due to vomiting and diarrhea
- If you suffer from symptoms of peritonitis: the drained dialysis solution is cloudy, abdominal pain, malaise, fever or in rare cases blood poisoning. Show the bag containing the drained dialysate to the physician.

Warnings:

Creatinine and urea levels should be monitored regularly during treatment with this medicine, as well as sugar levels, electrolytes (sodium, potassium, calcium, magnesium, phosphorus) acid-base balance and proteins in the blood, body weight, parathyroid hormones levels, renal function.

In diabetic patients, make sure to adjust the insulin dosage in accordance with the absorption of glucose in dialysis patients. Sugar levels should be checked on a regular basis.

Patients taking digitalis preparations should have blood potassium levels checked regularly.

If you are sensitive to any type of food or medicine, inform your physician before commencing treatment with this medicine.

Be sure to maintain a balanced diet to prevent water-soluble vitamin deficiencies.

Drug Interactions:

If you are taking another drug concomitantly or if you have just finished treatment with other medicine, inform the attending physician in order to prevent hazards or lack of efficacy arising from drug interactions. Especially with respect to medicines belonging to the following groups: diuretics, diabetic medicines given orally or insulin, calcium compounds or vitamin D. Potassium levels must be monitored particularly close during concurrent digitalis therapy.

Peritoneal dialysis treatment may affect the efficacy of medicines administered concurrently via the peritoneum. Other medications may be added only after they are found to be compatible with the dialysis solution.

Pregnancy and Breastfeeding:

There is insufficient information regarding the use of preparations during pregnancy and breastfeeding.

If you are pregnant or breastfeeding, consult a physician before using the medicine.

Side Effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine that may result from the technique of the peritoneal dialysis itself or may be induced by the dialysis solution, such as:

Effects related to mechanical reasons linked to the dialysis method:

Loss of proteins, amino acids and water-soluble vitamins, abdominal pain, fever, general malaise, peritonitis (cloudy solution), subcutaneous infection around the catheter manifested by redness, edema, discharge, formation of skin crusts and pain, abdominal bloating and feeling of fullness, difficulties with the flow of the dialysate, hernia, diarrhea, constipation, dyspnea, pain in the shoulder, general blood poisoning (sepsis)-rare.

Solution related adverse reactions:

Increase in blood sugar levels, electrolyte imbalance such as hypokalemia, hypercalcemia, fluid imbalance

that is detected by loss (dehydration) or increase (fluid accumulation) in body weight, low blood pressure, increase in heart rate, dizziness, high blood pressure, swollen legs, shortness of breath, changes in lipid profile in the blood, obesity (rare) as a result of prolonged glucose absorption, secondary overactive parathyroid gland that may cause disturbances in bone metabolism.

In any event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult a physician immediately.

Dosage:

The dosage is to be determined according to physician's instructions only. The treatment is carried out daily in accordance with the dosage.

Directions for use:

After appropriate training, dialysis may be performed independently at home. Ensure that all the instructions given during the training are followed exactly and maintain hygienic conditions when exchanging bags.

Make sure the solution is clear and that the bag is not damaged.

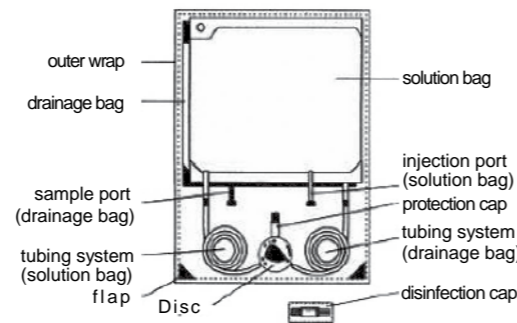
Maintain aseptic conditions and wash hands with anti-microbial soap.

Warm the solution to body temperature. It is not recommended to use a microwave.

The instillation time for each dose is 5-20 minutes.

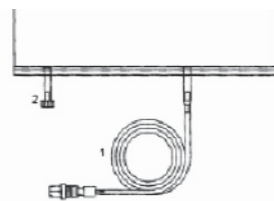
According to the physician's instructions, the solution should remain in the peritoneum for 2-10 hours and should then be drained.

Check the expiration date.



Stay-safe system (see diagram)

- Check the solution (expiry date, clarity and label). Remove the outer wrapping and the package of the disinfection cap.
- Wash your hands with anti-microbial soap.
- Place the DISC into the organizer (suspend the solution bag from the upper hole of the infusion pole - release the tube of the "solution bag-DISC" - place the DISC into the organizer - afterwards place drainage bag into lower holder of the infusion pole).
- Place catheter extension into the organizer.
- Disinfect your hands and remove protection cap of the DISC.
- Connect catheter extension into the DISC.
- Position "●" indicates that the outflow process has been operated.
- Flush position "●●" indicates that the flush of fresh dialysate to the drainage bag is occurring (approx. 5 seconds).
- Inflow position "○●●" indicates that there is a connection between solution bag and the catheter.
- Security step position – "●●●●" - automated closing of the catheter extension with the PIN.
- Disconnection – (remove catheter extension from the opening of the DISC) - screw the catheter extension to a new disinfection cap.
- Closing the DISC: Close the DISC with the open end of the protection cap (which is placed in the right hole of the organizer).
- Check the drained dialysate and dispose of it.



Sleep-safe system (see diagram)

- Preparing the solution:
 - Check the solution bag (expiry date, that the bag and external packaging are intact, clarity of the solution and label).
 - Place the bag on a solid surface
 - Open the over wrap
 - Wash your hands with an antimicrobial washing lotion
 - Ensure that the solution is clear and that the bag isn't leaking
- Unroll tubing (1) of the bag.
- Remove the protection cap.
- Insert connector in free sleep safe tray port.
- The bag is now ready for use with the sleep safe set.

Avoid poisoning!

This medicine and all other medicines, must be stored in a safe place out of the reach of children and/ or infants to avoid poisoning.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not induce vomiting, unless explicitly instructed to do so by a physician!

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

How to store the medicine?

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

Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medicines in the same package.

Additional Information:

In addition to the active ingredient, this medicine also contains:

Hydrochloric acid, sodium hydroxide, water for injections

What does the medicine look like?

CAPD products are colourless to slightly yellow clear solutions.

Drug registration number at the national medicines registry of the Ministry of Health:

CAPD 2: 107-95-26735

CAPD 3: 107-96-26734

CAPD 4: 107-97-26736

Manufacturer: Fresenius Medical Care Deutschland GmbH, Bad Homburg, Germany.

Registration Holder: NEPHROMED LTD. 7 Karlebach street, Tel-Aviv, Israel/