

Patient Information Leaflet

- 1. Product Name:** CAPD/DPCA 2, CAPD/DPCA 3, CAPD/DPCA 4,
- 2. Description of Product:** Solution for peritoneal dialysis

In this package leaflet CAPD/DPCA 2, CAPD/DPCA 3, and CAPD/DPCA 4 are referred to as "CAPD/DPCA" only.

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

3. What CAPD/DPCA contains

The active substances contained in one litre of each CAPD/DPCA solution are:

Sodium chloride	5.786 g
Sodium (S)-lactate solution (equivalent to 3.925 g sodium (S)-lactate)	7.85 g
Calcium chloride dihydrate	0.2573 g
Magnesium chloride hexahydrate	0.1017 g

These quantities of active substances are equivalent to:
134 mmol/l sodium ions, 1.75 mmol/l calcium ions, 0.5 mmol/l magnesium ions, 103.5 mmol/l chloride ions and 35 mmol/l lactate ions.

An additional active substance is:

CAPD/DPCA 2	
Glucose monohydrate equivalent to 15.0 g glucose (83.2 mmol/l)	16.5 g
CAPD/DPCA 3	
Glucose monohydrate equivalent to 42.5 g glucose (235.8 mmol/l)	46.75 g
CAPD/DPCA 4	
Glucose monohydrate equivalent to 22.73 g glucose (126.1 mmol/l)	25.0 g

The other ingredients of CAPD/DPCA are:
Water for injections, hydrochloric acid, sodium hydroxide

4. Strength of CAPD/DPCA

- 1.5 % Glucose 1.75 mmol/l Calcium for CAPD/DPCA 2
4.25 % Glucose 1.75 mmol/l Calcium for CAPD/DPCA 3
2.3 % Glucose 1.75 mmol/l Calcium for CAPD/DPCA 4

5. What CAPD/DPCA is and what it is used for

CAPD/DPCA is used for removing waste products from the blood and correcting abnormal levels of salts in the blood via the peritoneum in patients with end-stage chronic kidney failure. This type of blood cleaning is called peritoneal dialysis.

6. How much and how often should you use CAPD/DPCA

Always use CAPD/DPCA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Use CAPD/DPCA in the peritoneal cavity only.

Your doctor will determine the method, duration and frequency of use and the required volume of solution and retention time in the peritoneal cavity.

If tension in the abdominal region occurs the volume must be reduced.

Continuous ambulatory peritoneal dialysis (CAPD):

- Adults: the usual dose is 2,000 ml solution four times daily depending on body weight and kidney function.

Smaller or larger doses can be administered as appropriate (dose given merely as a guide, dosage must be adjusted for the individual patient).

Bags are exchanged over 24 hours. After 4 – 8 hours retention time the solution is drained off.

- Children up to 18 years of age: The doctor will determine the volume of dialysis solution required depending on the age, height and body weight.

The recommended dose is 30 – 40 ml/kg body weight.

Automatic peritoneal dialysis (APD):

Bag exchange is controlled automatically by the machine over night. For this, the CAPD/DPCA *s/leep•safe* system or the CAPD/DPCA *Safe•Lock* system is used.

Use CAPD/DPCA only if the solution is clear and the bag is undamaged.

Each CAPD/DPCA bag should be used only once and any unused solution remaining must be discarded.

After appropriate training, CAPD/DPCA 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 "Take special care with CAPD/DPCA".

7. Before you use CAPD/DPCA

Do not use CAPD/DPCA

- if the level of potassium in your blood is very low
- if the level of calcium in your blood is very high

In addition, do not use CAPD/DPCA 3 because CAPD 3 contains high concentration of glucose which is osmotic agent

- if the volume of your body fluids is too low } 1-A, 8-D
- if you have low blood pressure

Peritoneal dialysis treatment should not be started in the case of

5-A,
6-B
8-E

- alterations in the abdominal region such as
 - injuries or after surgery 1-C
 - severe burns
 - large inflammatory skin reactions
 - inflammation of the peritoneum
 - non-healing weeping wounds
 - umbilical, inguinal or diaphragmatic hernias 4-F
 - ulcers
- inflammatory bowel diseases 1-C
- intestinal obstruction 4-E, 4-G
- lung diseases, particularly pneumonia 5-B
- blood poisoning
- a disorder of metabolism known as lactic acidosis 5-H
- 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 1-B, 3-B

8. Possible side effects

Like all medicines, CAPD/DPCA can cause side effects, although not everybody gets them. The following side effect occurs when CAPD/DPCA is used:

Very common, more than 1 in 10 persons treated

5-E

- potassium deficiency 8-J

Side effects of CAPD/DPCA with unknown frequency are:

8-I, 2-G
5-E
5-F
1-B, 1

- calcium excess if the calcium intake is too high
- body fluid levels too low, which can be recognized by rapid weight loss, low blood pressure, rapid pulse
- body fluid levels too high, which can be recognized by water in the tissues and lung, high blood pressure, breathing difficulties
- high blood sugar levels } 2-D
- high blood fat levels }
- weight gain

8-J

The following side effects occur as a result of the treatment:

Very common, more than 1 in 10 persons 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.
- 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

3-A 4-E

Please contact your doctor immediately if you notice any of these side effects.

Other side effects of the treatment are:

- problems with inflow or outflow of the dialysate
- diarrhea
- constipation
- breathing difficulties due to elevation of the diaphragm
- sensation of stretching or fullness of the abdomen

8-J { 2-C
4-A
4-B
5-D
4-D

- shoulder pain A-G

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

9. What other medicine or food should be avoided whilst this medicine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Because blood cleaning may influence the effects of medicines, your doctor may need to change their dosages, especially those of

- medicines for heart failure, such as digoxin. Your doctor will check the level of potassium in your blood and, if necessary, will take appropriate measures. 1-D.1
- medicines that influence calcium levels such as those containing calcium or vitamin D. 8-H
- medicines that increase the excretion of urine, as hydrochlorothiazide. (high renal clearance) 1-D
- medicines taken by mouth that lower blood sugar levels or insulin. Your blood sugar level should be measured regularly. 1-D.1

10. If you forget to use CAPD/DPCA

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 your doctor if you are not sure.

11. How to store CAPD/DPCA

Keep out of the reach and sight of children.
Do not store CAPD/DPCA above 25°C. Do not refrigerate or freeze.
Do not use CAPD/DPCA after the expiry date printed on the bag and carton.

12. If you use more CAPD/DPCA than you should

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.

13. Marketing Authorization Holder

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14. Take special care with CAPD/DPCA

Inform your doctor immediately if you have

- a severe loss of electrolytes due to vomiting and/ or diarrhea 8-C
- an inflammation of the peritoneum, recognizable 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.

Blood cleaning 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. Your doctor will check your electrolyte balance, blood counts, kidney function, body weight and nutritional state.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding you should use CAPD/DPCA only if your doctor considers this absolutely necessary, because there is only limited experience in these groups.

} 6-P, 8-G

Driving and using machines

No special precautions are required.

8-G

If you stop using CAPD/DPCA

If you stop the blood cleaning without starting an alternative treatment, there can be life-threatening consequences.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

} 6-H

What CAPD/DPCA looks like and contents of the pack

The solution is clear and colorless to slightly yellowish.

CAPD/DPCA is available in the following application systems and pack sizes per carton:

<i>stay•safe</i> ®
6 bags each containing 1,500 ml 4 bags each containing 2,000 ml 4 bags each containing 2,500 ml
<i>sleep•safe</i>
2 bags each containing 5,000 ml 2 bags each containing 6,000 ml
Safe•Lock
2 bags each containing 5,000 ml 2 bags each containing 6,000 ml

Not all pack sizes may be marketed.

Handling instructions

stay•safe® system for continuous ambulatory peritoneal dialysis (CAPD):

1-C-1

The solution bag is first warmed to body temperature.

This should be done by using an appropriate heater tray. The heating time for a 2,000 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. Preparation of the solution

→ Check the warmed solution bag (label, expiry date, clearness of the solution, bag and over wrap not damaged, peel seams intact). → Place the bag on a solid surface. → Open the overwrap of the bag and the packaging of the disinfection cap. → Wash your hands with an antimicrobial washing lotion. → Check that the solution is clear and that the bag is not leaking.

2. Preparation of the bag exchange

→ Hang the solution bag in the upper hole of the infusion pole, unroll the tubing line of the solution bag, and place the DISC into the organizer. After unrolling the tubing line to the drainage bag, hang the drainage bag in the lower hole of the infusion pole and place the disinfection cap into the organizer. → Place catheter connector into the organizer. → Disinfect your hands and remove the protection cap of the DISC. → Connect catheter connector to the DISC.

3. Outflow

→ Open the catheter extension clamp. The outflow starts. → Position ●

4. Flush

→ After completion of outflow fill the tube between solution bag and DISC completely with fluid by flushing fresh solution into the drainage bag (approx. 5 seconds). → Position ●●

5. Inflow

→ Start inflow by turning the control switch to → Position ○●●

6. Safety step

→ Close the catheter extension by introducing the PIN into the catheter connector. → Position ●●●●

7. Disconnection

→ Remove protection cap from the new disinfection cap and screw it to the old one. → Screw the catheter connector off the DISC and screw the catheter connector to the new disinfection cap.

8. Closure of 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.

9. Check the drained dialysate for clarity and weight and if the effluent is clear discard it.

sleep•safe system and Safe•Lock system for automatic peritoneal dialysis (APD):

During automatic peritoneal dialysis (APD) the solution is warmed automatically by the machine.

sleep•safe system

1. Preparation of the solution

→ see *stay•safe*® system

2. Unroll tubing of solution bag.

3. Remove the protection cap.

4. Insert bag connector in free tray port of the cyclor.

5. The bag is now ready for use with the *sleep•safe* set.

Safe•Lock system

1. Preparation of the solution

→ see *stay•safe*® system

2. Remove protective cap of the connector from the connecting line.

3. Connect lines to the bag.

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.

15. Date of last revision: 05/2013