



**FRESENIUS
MEDICAL CARE**

CAPD/DPCA 4 *stay•safe link*

Philippines Package Insert



Peritoneal Dialysis Solution with
2.3% Dextrose

CAPD/DPCA 4 Stay Safe Link
Solution for Peritoneal Dialysis

In this insert

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1. DESCRIPTION

What Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)

The active substances contained in one litre of each **Peritoneal Dialysis Solution with 2.3% Dextrose** (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) solutions are:

Sodium chloride	5.786 g
Sodium-(S)-lactate-solution (equivalent to 3.925 g Sodium-(S)- lactate)	7.85 g
Calcium chloride dihydrate	257.3 mg
Magnesium chloride hexahydrate	101.7 mg

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:

Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)	
Glucose monohydrate equivalent to 22.73 g glucose (126.1 mmol/l)	25 g

The other ingredients of Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) are:

Water for injection, hydrochloric acid, sodium hydroxide

2. INDICATIONS

Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) is used for cleaning the blood via the peritoneum in patients with endstage chronic kidney failure. This type of blood cleaning is called peritoneal dialysis.

Read all of this insert carefully before the patient starts using this medicine.

- Keep this insert. The patient may need to read it again.
- If the patient has any further questions, please ask his doctor or pharmacist.
- This medicine has been prescribed for one patient. Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the adverse effects gets serious, or if the patient notices any adverse effects not listed in this insert, please tell the patient to ask his doctor or pharmacist.

3. CONTRAINDICATIONS

Do not use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)

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

Peritoneal dialysis treatment should not be started in the case of

- 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
 - ulcers
- inflammatory bowel diseases
- intestinal obstruction
- lung diseases, particularly pneumonia
- blood poisoning
- a disorder of metabolism known as lactic acidosis
- 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

blood counts, kidney function, body weight and nutritional state.

Using other medicines

Please ask the patient to tell his doctor or pharmacist if he is taking or has recently taken any other medicines, including medicines obtained without a prescription. Because blood cleaning may influence the effects of medicines, the doctor may need to change the patient's dosages, especially those of

- medicines for heart failure, such as digoxin. The doctor will check the level of potassium in 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, as hydrochlorothiazide.
- medicines taken by mouth that lower blood sugar levels or insulin. Blood sugar level should be measured regularly.

Pregnancy and breast-feeding

If the patient is pregnant or breast-feeding she should use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) only if her doctor considers this absolutely necessary, because there is only limited experience in this group.

Driving and using machines

No special precautions are required.

4. WARNING AND PRECAUTIONS

Take special care with Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)

Please ask the patient to inform his doctor immediately if the patient has

- a severe loss of electrolytes due to vomiting and/ or diarrhoea
- an inflammation of the peritoneum, recognizable by a cloudy dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning. Please ask the patient to show the bag containing the drained dialysate to his 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. The doctor will check the patient's electrolyte balance,

5. DOSAGE AND ADMINISTRATION

Always use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) exactly as advised by the doctor. The patient should check with doctor or pharmacist if anything not sure.

The 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 and elderly: the usual dose is 2000-3000ml solution four times daily depending on body weight and kidney function.

Bags are exchanged over 24 hours. After 2 – 10 hours retention time, the solution is drained off.

- Use in 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 initial dose is 600-800ml/m² (up to 1000ml/m² overnight) body surface area four times daily.

Use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) in the peritoneal cavity only.

Use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) only if the solution is clear and the bag is undamaged.

Handling instructions

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

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 the patient can start with the exchange of the bags.

1. Check the solution bag (label, expiry date, clearness of the solution, bag and over wrap not damaged) ♦ open the over wrap and package of the disinfection cap.
2. Clean your hands with an antimicrobial washing solution.
3. Place the DISC into the organiser (suspend solution bag from the upper hole of the infusion pole ♦ unroll the line “solution bag - DISC” ♦ place the DISC into the organiser ♦ place drainage bag into lower holder of the infusion pole).
4. Place catheter extension into the organiser.
5. Disinfect your hands and remove protection cap of the DISC.
6. Connect catheter extension to the DISC.
7. Open the clamp on extension ♦ position “●” ♦ outflow procedure starts.
8. 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 catheter extension by putting in the PIN.
11. Disconnection (remove catheter extension from the DISC) ♦ screw the new disinfection cap to the catheter extension.
12. Close the DISC. Close the DISC with the open end of the protection cap of the used disinfection cap (placed in the right hole of the organizer).
13. Check the drained dialysate and disposal.

Each Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) bag should be used only once and any unused solution remaining must be discarded.

After appropriate training, Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) can be used independently at home. Ensure that the patient follows all the procedures which has learned during training and maintain hygienic conditions when exchanging bags.

Always check the drained dialysate for cloudiness. See section 4 “Take special care ...”.

If the patient uses more Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) than he should

If the patient allows too much solution to flow into the peritoneal cavity, the excess can be drained off. If the patient uses too many bags please contact his doctor as this can result in fluid and/or electrolyte imbalances.

If the patient forgets to use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)

Try to attain the volume of dialysate prescribed for each 24-hour period in order to avoid the risk of possibly life-threatening consequences. The patient should check with his doctor if anything not sure.

If the patient stops using Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis)

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

If the patient has any further questions on the use of this product, please ask his doctor or pharmacist.

6. POSSIBLE ADVERSE EFFECTS

Like all medicines, this medicine can cause adverse effects, although not everybody gets them.

The assessment of the adverse effects is based on the following frequencies:

very common:	may affect more than 1 in 10 people
common:	may affect up to 1 in 10 people
uncommon:	may affect up to 1 in 100 people
rare:	may affect up to 1 in 1,000 people
very rare:	may affect up to 1 in 10,000 people
not known:	frequency cannot be estimated from the available data

The following adverse effects may occur as a result of the treatment:

very common

- 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 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.

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

Other adverse effects of the treatment are:

common:

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

uncommon:

- diarrhoea
- constipation

not known:

- breathing difficulties due to elevation of the diaphragm

The following adverse effects may occur when Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) is used:

very common:

- potassium deficiency

common:

- high blood sugar levels
- high blood fat levels
- weight gain
- calcium excess if the calcium level is too high

uncommon:

- 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 lung
- high blood pressure
- breathing difficulties

Reporting of adverse effects

If you get any adverse effects, talk to your doctor or nurse. This includes any possible adverse effects not listed in this insert. By reporting adverse effects you can help provide more information on the safety of this medicine.

7. STORAGE

Keep out of the reach and sight of children.

Store Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) below 30°C. Do not refrigerate or freeze.

Do not use Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) after the expiry date printed on the bag and carton.

The solution must be used immediately after first opening.

8. FURTHER INFORMATION

What Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) looks like and contents of the pack

The solution is clear and colourless to slightly yellowish.

Peritoneal Dialysis Solution with 2.3% Dextrose (CAPD/DPCA 4 Stay Safe Link Solution for Peritoneal Dialysis) is available in the following application systems and pack sizes per carton:

stay•safe link	6 bags each containing 2,000 ml
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Product License Holder/Importer/Distributor
Fresenius Medical Care Philippines Inc., 18/F, Aeon Center, corner Alabang-Zapote Road and North Bridgeway, Filinvest Corporate City, Alabang, Muntinlupa City, 1781, Philippines
DR-XY48485

Manufacturer

Fresenius Medical Care Production Sdn. Bhd.
Lot 34618, PT 29466
Techpark @ Enstek
71760 Bandar Enstek
Negeri Sembilan
Malaysia

Caution:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription. For suspected adverse drug reaction, report to FMCPI.PV@fmc-asia.com & FDA: www.fda.gov.ph.

This insert was last revised in February (Month) 2020 (Year).



**FRESENIUS
MEDICAL CARE**

CAPD/DPCA 4 *stay•safe link*

India Package Leaflet: Information for the user Peritoneal Dialysis Solution I.P. CAPD/DPCA 4

In This Leaflet

1. Indication
2. Contraindications
3. Warning & Precautions
4. Dosage & Administration
5. Possible Side Effects
6. Storage
7. Contents Of The Pack And Other Information

1. INDICATION

CAPD/DPCA 4 is **used for cleaning the blood** via the peritoneum in patients with end-stage chronic kidney failure. This type of blood cleaning is called peritoneal dialysis.

2. CONTRAINDICATIONS

Do not use CAPD/DPCA 4

- if the level of **potassium in your blood is very low**
- if the level of **calcium in your blood is very high**
- if you suffer from **disorders of lactate metabolism**
- if you have **fructose metabolism disorders** (hereditary fructose intolerance)

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
 - ulcers
- 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 cannot be treated by blood cleaning
- severe malnutrition and loss of weight, particularly if adequate intake of food containing proteins is not possible.

3. WARNING & PRECAUTIONS

Take special care with CAPD/DPCA 4

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

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs and illnesses are the same as yours.
- If you get any side effects gets serious, talk to your doctor pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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 (salt) balance, blood cell counts, kidney function, bodyweight and nutritional state.

CAPD/DPCA 4 contains 22.73 g glucose in 1000 ml solution. This should be taken into account in patients with diabetes mellitus.

Other medicines and CAPD/DPCA 4

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

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 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 hydrochlorothiazide.
- **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 you should use CAPD/DPCA 4 **only if your doctor considers this absolutely necessary**, because there is only limited experience in these groups.

Driving and using machines

When used as prescribed CAPD/DPCA 4 does not impair your ability to drive or operate machines.

4. DOSAGE & ADMINISTRATION

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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 and elderly:** The usual dose is 2000 - 3000 ml solution four times daily depending on body weight and kidney function. Bags are exchanged over 24 hours. After 2-10 hours retention time the solution is drained off.
- **Use in 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 initial dose is 600-800 ml/m² (up to 1000 ml/m² overnight) body surface area four times daily.

Use CAPD/DPCA 4 in the **peritoneal cavity only**.

Use CAPD/DPCA 4 only if the solution is clear and the bag is undamaged.

Handling instructions **stay•safe link system for continuous ambulatory peritoneal dialysis (CAPD):**

The solution bag is first warmed to body temperature. This should be done 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 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 over wrap not damaged) ♦ open the over wrap and package of the disinfection cap.
2. Clean your hands with an antimicrobial washing solution.
3. Place the DISC into the organiser (suspend solution bag from the upper hole of the infusion pole ♦ unroll the line "solution bag - DISC" ♦ place the DISC into the organiser ♦ place drainage bag into lower holder of the infusion pole).

- Place catheter extension into the organiser.
- Disinfect your hands and remove protection cap of the DISC.
- Connect catheter extension to the DISC.
- Open the clamp on extension → position "●" → outflow procedure starts.
- Flush → position "●●" → flush fresh dialysate to the drainage bag (approx. 5 seconds).
- Inflow → position "○○●" → connect the solution bag with the catheter.
- Security step → position "●●●●" → close catheter extension by putting in the PIN.
- Disconnection (remove catheter extension from the DISC) → screw the new disinfection cap to the catheter extension.
- Close the DISC. Close the DISC with the open end of the protection cap of the used disinfection cap (placed in the right hole of the organizer).
- Check the drained dialysate and disposal.

Each bag should be used only once and any unused solution remaining must be discarded. After appropriate training, CAPD/DPCA 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 3. **“Take special care with CAPD/DPCA 4”**

If you use more CAPD/DPCA 4 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.

If you forget to use CAPD/DPCA 4

In order to avoid the risk of possibly life-threatening consequences, you should contact your doctor.

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

5. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The assessment of the side effects is based on the following frequencies:

very common:	may affect more than 1 in 10 people
common:	may affect up to 1 in 10 people
uncommon:	may affect up to 1 in 100 people
rare:	may affect up to 1 in 1,000 people
very rare:	may affect up to 1 in 10,000 people
not known:	frequency cannot be estimated from the available data

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

very common

- 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 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.
- Please contact your doctor immediately if you notice any of these side effects.
- Other side effects of the treatment are:**
- common:**
- problems with inflow or outflow of the dialysate
 - sensation of stretching or fullness of the abdomen
 - shoulder pain
- uncommon:**
- diarrhoea
 - constipation
- not known:**
- breathing difficulties due to elevation of the diaphragm

The following side effect may occur when CAPD/DPCA 4 is used:

very common:

- potassium deficiency
- common:**
- high blood sugar levels
 - high blood fat levels
 - weight gain
 - calcium excess if the calcium level is too high

uncommon:

- 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 lung
- high blood pressure
- breathing difficulties

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

6. STORAGE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date printed on the bag and carton.

Store below 30°C. Do not refrigerate or freeze. The solution must be used immediately after first opening.

7. CONTENTS OF THE PACK AND OTHER INFORMATION

What CAPD/DPCA 4 contains

The active substances in one litre solution are:

Glucose monohydrate (equivalent to 22.73 g glucose)	25.0 g
Fructose up to 1.1 g	
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:

126.1 mmol/l glucose, 134 mmol/l sodium, 1.75 mmol/l calcium, 0.5 mmol/l magnesium, 103.5 mmol/l chloride and 35 mmol/l lactate. The other ingredients of CAPD/DPCA 4 are water for injections, hydrochloric acid, sodium hydroxide.

What CAPD/DPCA 4 looks like and contents of the pack

CAPD/DPCA 4 is a solution for peritoneal dialysis. The solution is clear and colourless to slightly yellow.

The theoretical osmolality of the solution is 401 mosm/l, the pH is about 5.5.

CAPD/DPCA 4 is available in the following application systems and pack sizes per carton:

stay•safe link
6* 2000 ml bags

Imported by

Fresenius Medical Care India Pvt. Ltd., B7 & B8, Middle Portion, SIPCOT Industrial Park, Irungattukottai, Sriperumbudur, Chennai, 602105, India

Marketed by

Fresenius Medical Care India Pvt. Ltd. S-21, Second Floor, Star City, District Centre, Mayur Palace, Mayur Vihar Phase- 1, New Delhi 110091

Manufactured by

Fresenius Medical Care Production Sdn. Bhd. Lot 34618, PT 29466 Techpark @ Enstek 71760 Bandar Enstek Negeri Sembilan Malaysia

Shelf Life - 24 Months

IN CASE OF CONSUMER COMPLAINTS, PLEASE CONTACT FRESenius MEDICAL CARE INDIA PVT. LTD. SAS TOWER-A, GROUND FLOOR, THE MEDICITY, SECTOR-38, GURUGRAM-122001, HARYANA, INDIA. TOLL FREE NO:- 18001209500 EMAIL ID: CUSTOMERSERVICE. INDIA@FMC-ASIA.COM

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