CAPD/DPCA stay safe

solution for peritoneal dialysis

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CAPD/DPCA stay safe peritoneal dialysis solutions and how they are used.

It does not contain all available information. It does not take the place of talking to your doctor or nurse.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about using CAPD/DPCA stay safe, ask your doctor or nurse.

Keep this leaflet with the medicine. You may need to read it again.

What CAPD/DPCA stay safe is used for

CAPD/DPCA stay safe is a clear sterile solution for peritoneal dialysis containing electrolytes and glucose with a neutral pH, supplied in double chamber flexible plastic bags. The solution bag comes with a system disc connector, a rotating switch and a drainage bag in a clear protective overwrap.

CAPD/DPCA stay safe is used to treat acute and chronic kidney failure. It helps with the removal of waste products and excess fluid from your blood when your kidneys do not work properly.

Before you use CAPD/DPCA stay safe

When you must not use it

CAPD/DPCA stay safe must not be used for intravenous infusion.

Do not use CAPD/DPCA stay safe:

- if the expiry date on the pack has passed
- if the packaging shows signs of being damaged or tampered with, or if you think it may be damaged
- if the solution in the bag looks cloudy or has small specks in it
- if you have low potassium levels (hypokalaemia)

Do not use CAPD/DPCA 2, 3, 4 stay safe solutions:

• if you have high calcium levels (hypercalcaemia)

Do not use CAPD/DPCA 10, 11, 12, 17, 18, 19 stay safe solutions:

• if you have low calcium levels (hypocalcaemia)

Do not use CAPD/DPCA 3, 4, 11, 12, 18, 19 stay safe solutions:

- if you have low blood pressure or are dehydrated
- if you have suffered acute blood loss or have muscle wastage

Before you start to use it

Tell your doctor if:

- you are pregnant, or are trying to become pregnant, or are breast-feeding
- you have high blood cholesterol or fat levels (hyperlipidemia)
- you have a hernia

- you have had any recent stomachrelated problems, including injury or surgery, infection, tumor or burns
- you have had peritonitis
- you have a lung disease, especially pneumonia
- you have an inflammation of your bowel (Crohn's disease, diverticulitis, ulcerative colitis)
- you have inflammatory abdominal skin reaction (dermatitis)
- you have non-healing weeping wounds (abdominal fistulae)
- you have had metabolic disorders (lactic acidosis); generalised blood poisoning (sepsis); in cases of accumulation of uraemic toxins in the blood (uraemia) the elimination of which can't be managed by peritoneal dialysis
- you have an intestinal blockage (ileus)
- you have diarrhoea and/or vomjtjng
- you have lost a lot of weight recently
- you are dehydrated or have low blood pressure
- you are taking digitalis. Your potassium levels must be checked regularly by your doctor, to see your potassium levels do not get too low

you are taking any other • medicines, including those that you buy without a prescription from a pharmacy, supermarket or a health food shop. It is especially important to inform your doctor if you are using insulin or other blood sugar reducing drugs, digitalis, drugs that influence the calcium level (calcium-containing phosphate binders, vitamin D) or that increase the output of urine (diuretics). Peritoneal dialysis may affect how they work in the body. Your doctor will advise you.

Should any of the above-mentioned disorders develop during peritoneal dialysis treatment, please consult your doctor who will decide how to proceed.

How to use CAPD/DPCA stay safe

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Adults: Unless otherwise advised, 2000 mL of dialysis solution should be slowly infused (over 5-20 minutes) into the peritoneal cavity using a permanent catheter. After a dwell time between 2 and 10 hours the solution should be drained.

Children: In children, a dose of 250 - 1500 mL per treatment (30 -40 mL/kg body weight) is recommended, depending on age, height and body weight.

Qualified nurses will train you in the use of CAPD/DPCA stay safe at the hospital or the dialysis clinic.

Your doctor will make certain that you can carry out peritoneal dialysis correctly before you are discharged from the hospital or dialysis clinic, and before you do it at home. You must follow the procedures and instructions given by your nurse every time you do peritoneal dialysis.

Contact your doctor if you are having problems or are unsure about any of the techniques.

How to use it

To change the dialysis bag, it is of vital importance that you carefully follow the steps that have been shown to you during training.

Aseptic techniques must be maintained during the bag connection in order to reduce the risk of infection.

Only use CAPD/DPCA stay safe if the solution is clear and the container undamaged.

Any unused portion of the solution must be discarded.

It is for use in one patient on one occasion only.

- 1. Wash your hands with an antiseptic lotion and dry them thoroughly before beginning the bag exchange.
- 2. Warm the solution bag to body temperature using the Fresenius Thermosafe bag warmer. Do not use a microwave to warm the solution.
- 3. Infuse the solution over 5 to 20 minutes through the peritoneal dialysis catheter into the peritoneal cavity.

If you forget to use CAPD/DPCA stay safe

Peritoneal dialysis should be carried out every day.

If you forget to do an exchange or have used too little solution, you must try to reach the total dialysate volume per 24 hours prescribed (e.g. 4 x 2000 mL for an adult), to avoid life-threatening consequences. Contact your doctor who will tell you exactly what to do.

If you use too much CAPD/DPCA stay safe (overdose)

If your stomach feels tight and very uncomfortable, you may have let too much solution flow in. **You can** easily drain it into an empty bag.

However, if you have made your bag exchanges too often, you may be dehydrated and/or have an electrolyte imbalance. **In this case please consult your doctor.**

While you are using CAPD/DPCA stay safe

Things you must do

Follow the procedures and instructions from your nurse or doctor on how to carry out peritoneal dialysis with CAPD/DPCA stay safe every time you do it. Always perform peritoneal dialysis regularly, as your doctor has told you to, even if you are not suffering any symptoms.

Body weight, nutritional state, serum electrolyte concentrations, acid-base status, blood proteins, serum creatinine and urea, indicators of bone metabolism and residual renal function should be monitored regularly by your doctor.

If you are feeling tired or unwell, or think you need to dialyse more frequently, please discuss it with your doctor or nurse.

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

Things you must not do

Do not use CAPD/DPCA stay safe for intravenous infusion.

Do not heat CAPD/DPCA stay safe in the microwave.

It can get too hot and burn you inside the abdominal cavity.

Use the Fresenius Thermosafe bag warmer to warm the solution to body temperature.

It will not overheat the solution.

Do not stop using CAPD/DPCA stay safe without letting your doctor know.

Life threatening accumulation of fluid in the tissues and lungs, or other symptoms of urea poisoning may appear.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are using CAPD/DPCA stay safe.

This medicine helps most people with end-stage chronic renal failure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- abdominal distension and feeling of fullness
- slow inflow or outflow of the dialysis solution
- hernia
- shoulder pain
- shortness of breath due to elevation of the diaphragm
- diarrhoea and constipation

Tell your doctor or pharmacist as soon as possible if you notice any of the following:

 peritonitis (with cloudy fluid in the drainage bag, abdominal pain, nausea and vomiting, fever, chills and, if untreated, generalised blood poisoning)

- inflammation around the catheter (at the exit side and along the tunnel)
- fluid and electrolyte imbalances, such as increased or decreased potassium and calcium levels
- symptoms of overhydration (e.g. oedema, shortness of breath)
- symptoms of dehydration (e.g. dizziness, muscle cramps)
- increased blood sugar levels
- obesity due to continuous glucose uptake
- disorders of lipid metabolism

After using CAPD/DPCA stay safe

Storage

Keep unopened CAPD/DPCA stay safe bags in a cool dry place where the temperature CAPD/DPCA stays below 25°C.

Do not refrigerate.

Keep CAPD/DPCA stay safe bags together with the supplies and equipment for your peritoneal dialysis treatments in a place where children cannot reach them.

Do not use after the expiry date on the bag.

Product description

What CAPD/DPCA stay safe looks like

CAPD/DPCA stay safe is a clear sterile solution containing electrolytes and glucose for peritoneal dialysis in double chamber flexible plastic bags, with a tubing system, a system connector with a rotating switch, and a drainage bag. It is available in 1.5 L, 2 L, 2.5 L and 3 L bags.

Ingredients

CAPD/DPCA stay safe contains glucose, sodium chloride, sodium (S)-lactate, calcium chloride, and magnesium chloride. The other ingredients are water for injections, hydrochloric acid, sodium hydroxide and sodium bicarbonate. It does not contain any antimicrobial preservative.

Note: sodium (S)-lactate is equivalent to sodium lactate; sodium bicarbonate is equivalent to sodium hydrogen carbonate.

The formulations are as follows:

Solutions containing calcium 1.75 mmol/L

<i>CAPD/DPCA 2 stay •safe</i> AUST R 62010	
Glucose anhydrous	1.50%
Sodium	134 mmol/L
Calcium	1.75 mmol/L
Magnesium	0.5 mmol/L
Chloride	101.5 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

<i>CAPD/DPCA 3 stay•safe</i> AUST R 62011	
Glucose anhydrous	4.25%
Sodium	134 mmol/L
Calcium	1.75 mmol/L
Magnesium	0.5 mmol/L
Chloride	101.5 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

<i>CAPD/DPCA 4 stay •safe</i> AUST R 62012	
Glucose anhydrous	2.3%
Sodium	134 mmol/L
Calcium	1.75 mmol/L
Magnesium	0.5 mmol/L
Chloride	101.5 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

Solutions containing calcium 1.0 mmol/L

CAPD/DPCA 10 stay •safe AUST R 62013	
Glucose	1.65%
Sodium	134 mmol/L
Calcium	1.0 mmol/L
Magnesium	0.5 mmol/L
Chloride	100 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

CAPD/DPCA 11 stay •safe AUST R 62014	
Glucose	4.675%
Sodium	134 mmol/L
Calcium	1.0 mmol/L
Magnesium	0.5 mmol/L
Chloride	100 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

CAPD/DPCA 12 stay •safe AUST R 62158	
Glucose	2.5%
Sodium	134 mmol/L
Calcium	1.0 mmol/L
Magnesium	0.5 mmol/L
Chloride	100 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

Solutions containing calcium 1.25 mmol/L

CAPD/DPCA 17 stay •safe AUST R 62015	
Glucose	1.65%
Sodium	134 mmol/L
Calcium	1.25 mmol/L
Magnesium	0.5 mmol/L
Chloride	100.5 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

CAPD/DPCA 18 stay •safe AUST R 62016	
Glucose	4.675%
Sodium	134 mmol/L
Calcium	1.25 mmol/L
Magnesium	0.5 mmol/L
Chloride	100.5 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

CAPD/DPCA 19 stay •safe AUST R 62017	
Glucose	2.5%
Sodium	134 mmol/L
Calcium	1.25 mmol/L
Magnesium	0.5 mmol/L
Chloride	100.5 mmol/L
Lactate	35 mmol/L
Bicarbonate	2 mmol/L

Further Information

Consult your doctor or dialysis unit for further information on your prescribed treatment.

Supplier

CAPD/DPCA stay safe is supplied in Australia by:

Fresenius Medical Care Australia Pty. Ltd. 305 Woodpark Road

Smithfield NSW 2164 Australia

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