

sleep safe balance

solution for peritoneal dialysis

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about sleep safe balance 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 sleep safe balance, ask your doctor or nurse.

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

What sleep safe balance is used for

sleep safe balance is a clear sterile solution for peritoneal dialysis containing electrolytes and glucose with a neutral pH, supplied in double chamber flexible plastic bags. The double chamber solution bag comes with a tubing system in a clear protective overwrap.

The sleep safe balance solutions can only be used with the sleep safe cyclor.

sleep safe balance 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 sleep safe balance

When you must not use it

sleep safe balance must not be used for intravenous infusion.

Do not use sleep safe balance:

- 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 sleep safe balance solutions containing 1.75 mmol calcium:

- if you have high calcium levels (hypercalcaemia)

Do not use sleep safe balance solutions containing 1.0 mmol calcium or 1.25 mmol calcium:

- if you have low calcium levels (hypocalcaemia)

Do not use sleep safe balance solutions containing 4.25% glucose:

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

Peritoneal dialysis in general must not be started:

- if you have, or have recently had, a disease of the abdominal wall or the cavity, including:
 - injury or surgery, burns,
 - hernia,
 - inflammatory abdominal skin reaction (dermatitis),
 - inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis),
 - peritonitis,
 - non-healing weeping wounds (abdominal fistulae),
 - intra-abdominal tumours,
 - intestinal obstruction (ileus).
- if you have a lung disease (especially pneumonia); metabolic disorders (lactic acidosis); generalised blood poisoning (sepsis); extreme weight loss (cachexia), particularly when adequate nutrition is impossible; in cases of accumulation of uraemic toxins in the blood (uraemia) the elimination of which can't be managed by peritoneal dialysis; or very high levels of fat in the blood (hyperlipidaemia).

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

Before you start to use it

Tell your doctor if:

- you are pregnant, or are trying to become pregnant, or are breast-feeding,

- you suffer from diabetes. Blood glucose levels must be monitored and the daily insulin dose or other treatments for hyperglycaemia adjusted by your doctor if required
- you have diarrhoea and/or vomiting,
- 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.

How to use sleep safe balance

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 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. This treatment is performed automatically by the sleep safe cyclor while you are asleep.

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 sleep safe balance with the sleep safe cyclor 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

For further information on the sleep safe cyclor, please refer to the Instructions Booklet that comes with the machine.

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 sleep safe balance if the solution is clear and the container undamaged. You must check the integrity of the middle seam before use.

The solutions in the two chambers must be mixed just before use.

The sleep safe cyclor automatically discards any unused portion of the solution.

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. **The solution bag is warmed to body temperature automatically by the sleep safe cyclor. You do not have to warm the solution beforehand.**
3. **Apply pressure on one solution chamber by rolling up the bag from one of the side edges until the middle seam opens. Due to the design of the bag the pressure will first open the middle seam allowing the mixture of both solutions by creating one single chamber.**
4. **Apply more pressure by rolling up the bag from the upper edge to break the seam of the solution-free outflow part. The solution is now ready to use.**
5. **Attach the bag to the sleep safe cyclor as instructed. The sleep safe cyclor will automatically infuse the mixed solution over 5 to 20 minutes through the peritoneal dialysis catheter into the peritoneal cavity.**
6. **The mixed ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing.**

If you forget to use sleep safe balance

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 sleep safe balance (overdose)

It should not be possible to use too much sleep safe balance, because the sleep safe cyclor automatically controls it.

If you think there has been a machine fault or an error in the program, please consult your doctor.

Your stomach will feel tight and very uncomfortable if too much solution has been instilled. If the exchanges have occurred too often, you may be dehydrated and/or have an electrolyte imbalance.

While you are using sleep safe balance

Things you must do

Follow the procedures and instructions from your nurse or doctor on how to carry out peritoneal dialysis with sleep safe balance 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 sleep safe balance does not impair your ability to drive or operate machines.

Things you must not do

Do not use sleep safe balance for intravenous infusion.

Do not heat sleep safe balance.

The sleep safe cyclor automatically heats it to the correct temperature.

Do not stop using sleep safe balance 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.

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

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

After using sleep safe balance

Storage

Keep unopened sleep safe balance bags in a cool dry place where the temperature stays below 25°C.

Do not refrigerate.

Keep sleep safe balance 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 sleep safe balance looks like

sleep safe balance is a clear sterile solution containing electrolytes and glucose for peritoneal dialysis in double chamber flexible plastic bags, with tubing system for connection to the sleep safe cyclor. It is available in a 1.5 L, 2 L, 2.5 L, 3 L and 5 L bags.

Ingredients

sleep safe balance 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 1.0 mmol/L

<i>sleep safe balance</i> 1.5% glucose, 1.0 mmol/L calcium AUST R 92933	
Glucose anhydrous	1.50%
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

<i>sleep safe balance</i> 4.25% glucose, 1.0 mmol/L calcium AUST R 92942	
Glucose anhydrous	4.25%
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

<i>sleep safe balance</i> 2.3% glucose, 1.0 mmol/L calcium AUST R 92936	
Glucose anhydrous	2.3%
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

<i>sleep safe balance</i> 1.5% glucose, 1.25 mmol/L calcium AUST R 92934	
Glucose anhydrous	1.50%
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

<i>sleep safe balance</i> 4.25% glucose, 1.25 mmol/L calcium AUST R 92943	
Glucose anhydrous	4.25%
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

<i>sleep safe balance</i> 2.3% glucose, 1.25 mmol/L calcium AUST R 92937	
Glucose anhydrous	2.3%
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

Solutions containing calcium 1.75 mmol/L

<i>sleep safe balance</i> 1.5% glucose, 1.75 mmol/L calcium AUST R 92935	
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>sleep safe balance</i> 4.25% glucose, 1.75 mmol/L calcium AUST R 92944	
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>sleep safe balance</i> 2.3% glucose, 1.75 mmol/L calcium AUST R 92938	
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

Further Information

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

Supplier

sleep safe balance is supplied in Australia by:
Fresenius Medical Care Australia Pty. Ltd.

305 Woodpark Road
Smithfield NSW 2164 Australia

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