

# sleep•safe balance

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using *sleep•safe balance*?

*sleep•safe balance* contains the active ingredients glucose monohydrate, calcium chloride dihydrate, sodium chloride, sodium (S)-lactate and magnesium chloride hexahydrate. *sleep•safe balance* is used to treat end-stage kidney disease and acute kidney failure. It helps with the removal of waste products and excess fluid from your blood when your kidneys do not work properly.

For more information, see Section [1. Why am I using \*sleep•safe balance\*?](#) in the full CMI.

### 2. What should I know before I use *sleep•safe balance*?

Do not use if you have ever had an allergic reaction to *sleep•safe balance* or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use \*sleep•safe balance\*?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with *sleep•safe balance* and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use *sleep•safe balance*?

- Follow all directions given to you by your doctor or pharmacist carefully.
- Qualified nurses will train you in the use of *sleep•safe balance* with a 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.

More instructions can be found in Section [4. How do I use \*sleep•safe balance\*?](#) in the full CMI.

### 5. What should I know while using *sleep•safe balance*?

Things you should do	<ul style="list-style-type: none"><li>Remind any doctor, dentist or pharmacist you visit that you are using <i>sleep•safe balance</i>.</li><li>Follow the instructions from your nurse or doctor on how to carry out peritoneal dialysis.</li><li>If you are feeling tired or unwell, discuss it with your doctor or nurse.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>Do not use <i>sleep•safe balance</i> for intravenous infusion.</li><li>Do not heat <i>sleep•safe balance</i> in the microwave.</li><li>Do not stop using <i>sleep•safe balance</i> without letting your doctor know.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>When used as prescribed <i>sleep•safe balance</i> does not impair your ability to drive or operate machines.</li></ul>
Looking after your medicine	<p>Store <i>sleep•safe balance</i> below 25°C. Do not refrigerate.</p> <ul style="list-style-type: none"><li>Do not use after the expiry date on the bag.</li><li>The ready to use solution should be used immediately, but within a maximum of 24 hours after mixing.</li><li>Each bag should be used only once and any unused solution remaining must be discarded.</li></ul>

For more information, see Section [5. What should I know while using \*sleep•safe balance\*?](#) in the full CMI.

### 6. Are there any side effects?

You may experience side effects such as hernia, shoulder pain, peritonitis, abdominal pain, inflammation around the catheter, fluid and electrolyte imbalances.

For more information, including full list of possible side effects and what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# sleep•safe balance

**Active ingredient(s):** Glucose monohydrate, calcium chloride dihydrate, sodium chloride, sodium (S)-lactate and magnesium chloride hexahydrate

## Consumer Medicine Information (CMI)

This leaflet provides important information about using *sleep•safe balance*. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using *sleep•safe balance*.**

**Where to find information in this leaflet:**

- [1. Why am I using \*sleep•safe balance\*?](#)
- [2. What should I know before I use \*sleep•safe balance\*?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use \*sleep•safe balance\*?](#)
- [5. What should I know while using \*sleep•safe balance\*?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using *sleep•safe balance*?

*sleep•safe balance* contains the active ingredients glucose monohydrate, calcium chloride dihydrate, sodium chloride, sodium (S)-lactate and magnesium chloride hexahydrate. *sleep•safe balance* is a solution for peritoneal dialysis.

*sleep•safe balance* is used for cleaning the blood via the peritoneum in patients with end-stage kidney disease or acute kidney failure. It helps with the removal of waste products and excess fluid from your blood when your kidneys do not work properly. This type of blood cleaning is called peritoneal dialysis.

### 2. What should I know before I use *sleep•safe balance*?

#### Warnings

**Do not use *sleep•safe balance* if:**

- the expiry date on the pack has passed
- the packaging shows signs of being damaged or tampered with, or if you think it may be damaged
- the solution in the bag looks cloudy or has small specks in it
- you are allergic to any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
- you have very low potassium levels (severe hypokalaemia)
- you have a disorder of metabolism known as lactic acidosis

**Do not use *sleep•safe balance* solutions containing 1.75 mmol calcium if:**

- you have very high calcium levels (severe hypercalcaemia)

**Do not use *sleep•safe balance* solutions containing 1.25 mmol calcium if:**

- you have very low calcium levels (severe hypocalcaemia)

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

- you have low blood pressure (arterial hypotension), or the volume of your body fluids is too low (hypovolaemia)

**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,
  - a history of abdominal operations with fibrous adhesions,
  - bowel perforations,
  - burns,
  - umbilical, inguinal or abdominal hernia,
  - large 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).
- you have a lung disease (especially pneumonia),
- you have generalised blood poisoning (sepsis),
- you have 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,
- you have very high levels of fat in the blood (hyperlipidaemia).

**Check with your doctor if you:**

- have a **severe loss of electrolytes (salts)** due to diarrhoea and/or vomiting
- have **abnormal kidneys** (polycystic kidneys)
- have an **inflammation of the peritoneum**, recognisable by a cloudy dialysate and/or abdominal pain. Please show the bag containing the drained dialysate to your doctor
- have **severe abdominal pain, abdominal distension or vomiting**. This can be a sign of encapsulating peritoneal

sclerosis, a complication of the peritoneal dialysis therapy that can be fatal.

- have any other medical conditions

for *sleep•safe balance* solutions containing 1.25 mmol calcium:

- have an **overactive parathyroid gland**. It may be necessary to take additionally calcium-containing phosphate binders and/or vitamin D.
- have **calcium levels which are too low**. It may be necessary to take additionally calcium-containing phosphate binders and/or vitamin D or to use a peritoneal dialysis solution with a higher calcium concentration.

for *sleep•safe balance* solutions containing 1.75 mmol calcium:

- have **calcium levels which are too high**. A temporary or permanent change to the peritoneal dialysis solution together with a lower calcium concentration should be considered.

Peritoneal dialysis 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Because peritoneal dialysis 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.
- **medicines that influence calcium levels** such as those containing calcium or vitamin D.
- **medicines that increase the excretion of urine**, such as diuretics.
- **medicines taken by mouth that lower blood sugar levels** or insulin. Your blood sugar level should be

measured regularly. Diabetic patients may need to adjust the daily dose of insulin.

Your doctor will advise you.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect *sleep•safe balance*.**

## 4. How do I use *sleep•safe balance*?

Always use *sleep•safe balance* exactly as your doctor or pharmacist 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 dwell time in the peritoneal cavity.

Qualified nurses will train you in the use of *sleep•safe balance* at the hospital or the dialysis clinic.

**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 much to use

- The mode of therapy, frequency of administration and dwell time required will be specified by the attending physician. Use of *sleep•safe balance* solutions must be made in conjunction with a **cycler**. Bag exchange is controlled automatically by the cycler over night.
- Adults: The usual prescription is 1500 mL to 3000 mL per exchange with 3 to 10 exchanges per night. The cycler therapy at night is usually combined with 1 or 2 exchanges during the daytime.
- Children: The volume per exchange should be 800 to 1000 mL/m<sup>2</sup> (can be increased up to 1400 mL/m<sup>2</sup>) body surface area with 5-10 exchanges overnight.
- If tension in the abdominal region occurs your doctor may reduce the volume.
- Follow the instructions provided and use *sleep•safe balance* until your doctor tells you to stop.

### When to use *sleep•safe balance*

*sleep•safe balance* should be used regularly, as prescribed by your doctor.

Qualified nurses will train you in the use of *sleep•safe balance* with the *sleep•safe* cycler 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 handle *sleep•safe balance* with the *sleep•safe* cyclor

- 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.
- 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.

- The mixed ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing.
- Any unused portion of the solution must be discarded.

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

### 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 to avoid life-threatening consequences.

Contact your doctor if you are not sure.

### If you use too much *sleep•safe balance*

If you allow too much solution to flow into the peritoneal cavity, the excess can easily be drained into the 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.**

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

If you think that you have used too much *sleep•safe balance*, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using *sleep•safe balance*?

### Things you should 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, phosphate, serum electrolyte concentrations, acid-base status, blood gases, blood proteins, serum creatinine and urea, indicators of bone metabolism, blood sugar and kidney 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.**

#### Call your doctor straight away if you:

- Do not feel well. This medicine helps most people with end-stage chronic renal failure, but it may have unwanted side effects. You may need medical attention if you get some of the side effects

Remind any doctor, dentist or pharmacist you visit that you are using *sleep•safe balance*.

### Things you should not do

- Do not use *sleep•safe balance* for intravenous infusion.
- Do not heat *sleep•safe balance* bag in the microwave. 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.

### Driving or using machines

*sleep•safe balance* has no or negligible influence on your ability to drive or operate machines.

## Looking after your medicine

- Store *sleep•safe balance* below 25°C. Do not refrigerate.
- **Keep it where young children cannot reach it.**

Follow the instructions in the carton on how to take care of your medicine properly.

## When to discard your medicine

The ready-to-use solution should be used immediately, or within a maximum of 24 hours after mixing. Unused solution remaining must be discarded.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>General disorders</b> <ul style="list-style-type: none"><li>• feeling unwell</li></ul> <b>Peritoneal dialysis procedure related disorders</b> <ul style="list-style-type: none"><li>• problems with inflow or outflow of the dialysis solution</li></ul> <b>Metabolism and nutrition disorders</b> <ul style="list-style-type: none"><li>• high levels of fats in the blood (eg. high cholesterol)</li></ul> <b>Gastrointestinal disorders</b> <ul style="list-style-type: none"><li>• hernia</li><li>• diarrhoea and constipation</li><li>• abdominal distension and feeling of fullness</li></ul> <b>Respiratory, thoracic and mediastinal disorders</b> <ul style="list-style-type: none"><li>• shoulder pain</li></ul> <b>Endocrine disorders</b> <ul style="list-style-type: none"><li>• overactive parathyroid with potential disturbance of the bone metabolism (solutions containing 1.25 mmol calcium)</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Infections</b> <ul style="list-style-type: none"><li>• peritonitis (with cloudy fluid in the drainage bag, abdominal pain, nausea and vomiting, fever, chills and, if untreated, generalised blood poisoning)</li></ul> <b>General disorders and administration/catheter site conditions</b> <ul style="list-style-type: none"><li>• inflammation or pain around the catheter (at the exit side and along the tunnel).</li><li>• symptoms of overhydration (e.g. swollen legs, shortness of breath, high blood pressure, increased body weight)</li><li>• symptoms of dehydration (e.g. dizziness, muscle cramps, low blood pressure, increased heart rate)</li></ul> <b>Renal disorders</b> <ul style="list-style-type: none"><li>• fluid and electrolyte imbalances, such as increased or decreased potassium and calcium levels</li></ul> <b>Metabolism and nutrition disorders</b> <ul style="list-style-type: none"><li>• increased blood sugar levels</li><li>• weight gain</li></ul> <b>Gastrointestinal disorders</b> <ul style="list-style-type: none"><li>• thickening and scarring of the peritoneum</li></ul> <b>Respiratory disorders</b> <ul style="list-style-type: none"><li>• shortness of breath eg. due to elevation of the diaphragm</li></ul> <b>Cardiac and vascular disorders</b> <ul style="list-style-type: none"><li>• increased heart rate</li><li>• low blood pressure</li><li>• high blood pressure</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

This leaflet was prepared in August 2024.

7. Product details

This medicine is only available with a doctor's prescription.

What *sleep•safe balance* contains

Active ingredients (main ingredients)	Glucose monohydrate, calcium chloride dihydrate, sodium chloride, sodium (S)-lactate, magnesium chloride hexahydrate
Other ingredients (inactive ingredients)	Water for injections, sodium hydroxide, sodium bicarbonate, hydrochloric acid

Do not take this medicine if you are allergic to any of these ingredients.

What *sleep•safe balance* looks like

*sleep•safe balance* is a clear sterile solution available in flexible, non-PVC double-chamber plastic bags, with tubing system for connection to a cyclor. One chamber contains the alkaline sodium lactate solution and the other the acidic glucose-based electrolyte solution. The system is covered by a clear protective overwrap.

It is available in cartons containing 4 bags of 3000 mL or 2 bags of 5000 mL, respectively.

Not all pack sizes may be marketed.

*sleep•safe balance* 1.5% glucose 1.25 mmol/L calcium:  
Aust R 92934

*sleep•safe balance* 2.3% glucose 1.25 mmol/L calcium:  
Aust R 92937

*sleep•safe balance* 4.25% glucose 1.25 mmol/L calcium:  
Aust R 92943

*sleep•safe balance* 1.5% glucose 1.75 mmol/L calcium:  
Aust R 92935

*sleep•safe balance* 2.3% glucose 1.75 mmol/L calcium:  
Aust R 92938

*sleep•safe balance* 4.25% glucose 1.75 mmol/L calcium:  
Aust R 92944

Who distributes *sleep•safe balance*

*sleep•safe balance* is supplied in Australia by:

Australian Sponsor:  
Fresenius Medical Care Pty Ltd  
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