

## PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

### Balance 1.5% glucose, 1.25 mmol/L calcium

### Balance 1.5% glucose, 1.75 mmol/L calcium

### Balance 2.3% glucose, 1.25 mmol/L calcium

### Balance 2.3% glucose, 1.75 mmol/L calcium

### Balance 4.25% glucose, 1.25 mmol/L calcium

### Balance 4.25% glucose, 1.75 mmol/L calcium

#### Solution for peritoneal dialysis

Composition:

Each liter of ready-to-use solution contains:

	Balance 1.5% glucose, 1.25 mmol/L calcium	Balance 2.3% glucose, 1.25 mmol/L calcium	Balance 4.25% glucose, 1.25 mmol/L calcium	Balance 1.5% glucose, 1.75 mmol/L calcium	Balance 2.3% glucose, 1.75 mmol/L calcium	Balance 4.25% glucose, 1.75 mmol/L calcium
Calcium chloride dihydrate	0.1838 g	0.1838 g	0.1838 g	0.2573 g	0.2573 g	0.2573 g
Sodium chloride	5.640 g	5.640 g	5.640 g	5.640 g	5.640 g	5.640 g
Sodium (S)-lactate solution (sodium (S)-lactate)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)	7.85 g (3.925 g)
Magnesium chloride hexahydrate	0.1017 g	0.1017 g	0.1017 g	0.1017 g	0.1017 g	0.1017 g
Glucose monohydrate (anhydrous glucose)	16.5 g (15.0 g)	25.0 g (22.73 g)	46.75 g (42.5 g)	16.5 g (15.0 g)	25.0 g (22.73 g)	46.75 g (42.5 g)
Ca <sup>2+</sup>	1.25 mmol	1.25 mmol	1.25 mmol	1.75 mmol	1.75 mmol	1.75 mmol
Na <sup>+</sup>	134 mmol	134 mmol	134 mmol	134 mmol	134 mmol	134 mmol
Mg <sup>2+</sup>	0.5 mmol	0.5 mmol	0.5 mmol	0.5 mmol	0.5 mmol	0.5 mmol
Cl <sup>-</sup>	100.5 mmol	100.5 mmol	100.5 mmol	101.5 mmol	101.5 mmol	101.5 mmol
(S)-Lactate	35 mmol	35 mmol	35 mmol	35 mmol	35 mmol	35 mmol
Glucose	83.2 mmol	126.1 mmol	235.8 mmol	83.2 mmol	126.1 mmol	235.8 mmol
Theoretical osmolarity	356 mOsm/l	399 mOsm/l	509 mOsm/l	358 mOsm/l	401 mOsm/l	511 mOsm/l
pH ≈	7.0	7.0	7.0	7.0	7.0	7.0

Inactive and allergenic ingredients – see section 6 “Further information” and section 2 “Before using the medicine”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine.

If you have further questions, refer to the doctor, pharmacist or nurse.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

#### 1. WHAT IS THE MEDICINE INTENDED FOR?

Balance solutions are intended for the treatment of patients who suffer from end-stage chronic renal failure who are being treated with peritoneal dialysis.

**Therapeutic group:** Peritoneal dialysis, hypertonic solutions

#### 2. BEFORE USING THE MEDICINE

<p><b>Do not use the medicine if:</b></p> <ul style="list-style-type: none"><li>• The level of <b>potassium in your blood is very low</b></li><li>• The level of <b>calcium in your blood is very low</b> (for 1.25 mmol/l calcium only)</li><li>• The level of <b>calcium in your blood is very high</b> (for 1.75 mmol/l calcium only)</li><li>• <b>Your body fluid volume is too low</b> (for 4.25% glucose only)</li><li>• You have <b>low blood pressure</b> (for 4.25% glucose only)</li><li>• You suffer from a <b>metabolic disorder called lactic acidosis</b></li></ul>
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#### Do not commence peritoneal dialysis if you have

##### • alterations in the abdominal region such as

- injuries or after surgery
- burns
- widespread inflammatory skin reactions
- peritoneal inflammation
- non-healing weeping wounds
- umbilical, inguinal or diaphragmatic hernia
- tumours in the abdomen or bowel

##### • inflammatory bowel diseases

- intestinal obstruction
- lung diseases, especially 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 weight loss, particularly if adequate intake of food containing proteins is not possible

#### **Special warnings regarding use of the medicine**

**Before starting treatment with Balance, inform the doctor immediately:**

- if you have an **overactive parathyroid gland**. It may be necessary to take additionally calcium-containing phosphate binders and/or vitamin D (for 1.25 mmol/l calcium only).

- if you have **calcium levels which are too low**. It may be necessary to take additionally calcium-containing phosphate binders and/or vitamin D or use a peritoneal dialysis solution with a higher concentration of calcium (for 1.25 mmol/l calcium only).

- if you suffer from **severe loss of electrolytes (salts)** due to vomiting and/or diarrhea.

- if you have **abnormal kidneys** (polycystic kidneys).

- if you suffer from a **peritoneal inflammation**, which can be identified by cloudy dialysate and/or abdominal pain. Please show your doctor the bag that contains the drained dialysis fluid.

- if you suffer from **severe abdominal pains, abdominal distension or vomiting**. These may be a sign of encapsulating peritoneal sclerosis, a potentially life-threatening complication of peritoneal dialysis.

Peritoneal dialysis can lead to **loss of proteins and water-soluble vitamins**. An adequate diet or nutritional supplements are recommended to avoid deficiency states. Your doctor will check your electrolyte (salt) balance, kidney function, body weight and nutritional state.

Due to the high glucose concentration, Balance 2.3% glucose and Balance 4.25% should be used cautiously and under monitoring by your doctor.

#### **Drug interactions:**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines or nutritional supplements, tell the doctor or pharmacist.** Because peritoneal dialysis may influence the effects of medicines, your doctor may have to change their dosages, especially 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 (for 1.75 mmol/l calcium only).

- **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.

#### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor before taking this medicine. There is not enough information about the use of Balance in pregnant women or while breast-feeding. Do not use Balance if you are pregnant or breast-feeding, **unless your doctor thinks it is absolutely necessary**.

#### **Driving and operating machinery**

Balance has no or negligible influence on the ability to drive and operate machinery.

#### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use the medicine according to the doctor's or pharmacist's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.

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

If tension in the abdominal region occurs, your doctor may reduce the volume.

**The dosage and treatment regimen will be determined by the doctor only.**

#### **The usual dosage is:**

##### **Continuous ambulatory peritoneal dialysis (CAPD):**

- **Adults:** The usual dose is 2000-3000 ml solution, four times a day, depending on body weight and kidney function.

After 2-10 hours of dwell time, the solution is drained.

- **Children:** The doctor will determine the volume of the dialysis solution required, depending on the child's tolerance, age and body surface area. The recommended initial dose is 600-800 ml/m<sup>2</sup> (up to 1000 ml/m<sup>2</sup> throughout the night) body surface area, four times a day.

#### **Automated peritoneal dialysis (APD):**

For this type, the sleep•safe or Safe•Lock system is used. Bag exchange is controlled automatically throughout the night by the cyclor machine.

- **Adults:** The usual prescription is 2000 ml (maximum 3000 ml) per exchange, with 3-10 exchanges during the night and 8-10 hours in the cyclor machine, and 1 or 2 exchanges during the day.

- **Children:** The volume per exchange should be 800-1000 ml/m<sup>2</sup> (up to 1400 ml/m<sup>2</sup>) body surface area, with 5-10 exchanges during the night.

#### **Do not exceed the recommended dose.**

Use Balance in the **peritoneal cavity only**.

Only use Balance if the solution is clear and the bag is undamaged.

Balance is available in a double-chamber bag. Before use, the solutions in the two chambers must be mixed, in accordance with the instructions.

#### **Instructions for use:**

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

First warm up the solution bag to body temperature. This should be done using an appropriate bag warmer. The heating time for a 2000 ml bag with a starting temperature of 22°C is approximately 120 minutes. More detailed information can be obtained from the operating instructions of the bag warmer. Do not use a microwave to warm up 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 overwrap 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. ⇒ Roll up the bag which is lying on the overwrap, from one of the side edges until the middle peel seam opens. The solutions in the two chambers are mixed automatically. ⇒ Now roll up the bag from the upper edge until the peel seam of the lower triangle is completely open. ⇒ Check whether all peel seams are completely open. ⇒ Check whether the solution is clear and that the bag is not leaking.

##### **2. Preparation of the bag exchange**

⇒ Hang the solution bag from 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 of the drainage bag, hang the drainage bag from the lower hole of the infusion pole. ⇒ Place the catheter connector into one of the two inserts of the organizer. ⇒ Place the new disinfection cap into the other free insert. ⇒ Disinfect your hands and remove the protection cap of the DISC. ⇒ Connect catheter connector to the DISC.

##### **3. Outflow**

⇒ Open the clamp on the catheter connector. The outflow starts.

- ⇒ Position ●

##### **4. Flush**

⇒ After completion of outflow, flush fresh solution into the drainage bag (approximately 5 seconds).

- ⇒ Position ●●

##### **5. Inflow**

⇒ Start inflow by turning the control switch

- ⇒ Position ●●○

##### **6. Safety step**

⇒ Close the catheter connector by introducing the PIN into the catheter connector. ⇒ Position ●●●

##### **7. Disconnection**

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

##### **8. Closure of the DISC**

⇒ Close the DISC with the open end of the used disinfection cap, which has remained 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 for automated peritoneal dialysis (APD):**

During APD, the solution is warmed automatically by the cyclor.

##### **3000 ml sleep•safe system:**

- 1. Preparation of the solution:** see stay•safe system

- 2. Unroll the tubing of bag.**

- 3. Remove the protection cap.**

- 4. Insert the bag connector into the free tray port of the sleep•safe cyclor.**

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

##### **5000 ml sleep•safe system:**

- 1. Preparation of the solution**

⇒ Check the solution bag (label, expiry date, clarity of the solution, bag, and overwrap not damaged, bag peel

seams intact). ⇒ Place the bag on a solid surface. ⇒ Open the overwrap of the bag. ⇒ Wash your hands with an antimicrobial washing lotion. ⇒ Unfold the middle peel seam and the bag connector. ⇒ Roll up the bag, which is lying on the overwrap, from the diagonal end towards the bag connector. The middle peel seam will open. ⇒ Continue until the peel seam of the small chamber opens as well. ⇒ Check that all peel seams are completely open. ⇒ Check that the solution is clear and that the bag is not leaking.

- 2. -5:** See sleep•safe 3000 ml system

##### **Safe•Lock system for automatic peritoneal dialysis (APD):**

During the APD, the solution is warmed automatically by the cyclor.

- 1. Preparation of the solution:** see 5000 ml sleep•safe system

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

- 3. Connect the 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.**

Use each bag only once and discard all unused solution remaining.

After appropriate training, Balance can be used independently, at home. To do so, be sure that you follow all the steps you learned during the training and strictly maintain hygienic conditions while exchanging the bags.

Always check the drained dialysate for cloudiness. See section 2.

#### **If you accidentally took a higher dosage**

If you allowed too much solution to flow into the peritoneal cavity, the excess can be drained. If you use too many bags, please refer to your doctor since this may cause an imbalance in fluids and/or electrolytes.

#### **If you forget to use this medicine**

Try to attain the volume of the dialysis solution prescribed for you for each 24-hour period, in order to avoid the risk of possibly life-threatening consequences. Check with your doctor if you are uncertain.

Adhere to the treatment regimen as recommended by the doctor.

**Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.**

**If you have further questions regarding use of the medicine, consult with the doctor, pharmacist or nurse.**

#### **4. SIDE EFFECTS**

As with any medicine, use of Balance may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

The following side effects may occur as a result of peritoneal dialysis treatment, generally:

**Very common side effects** effects that occur in more than one in ten users

- Inflammation of the peritoneum with signs of cloudiness of the drained dialysate, abdominal pains, fever, feeling unwell, and in very rare cases, blood poisoning. Show your doctor the bag containing the cloudy dialysate.
- Inflammation of the skin at the catheter exit site or along the catheter, which can be identified by onset of redness, swelling, pain, weeping or crusts.
- Abdominal wall hernia.

**Refer to your doctor immediately if you notice any of these side effects.**

Additional side effects of treatment are:

**Common side effects** effects that occur in 1-10 in 100 users

- Problems with dialysis fluid flow or drainage
- Sensation of stretching or fullness of the abdomen
- Shoulder pain

**Uncommon side effects** effects that occur in 1-10 in 1,000 users

- Diarrhea
- Constipation

**Very rare side effects** effects that occur in less than one user in 10,000

- Blood poisoning

**Side effects of unknown frequency** frequency cannot be estimated from the existing data

- Breathing difficulties
- Feeling unwell
- Encapsulating peritoneal sclerosis, possible symptoms may include abdominal pain, abdominal distension or vomiting

The following side effects may occur when Balance is used:

**Very common side effects** effects that occur in more than one user in ten

- Potassium deficiency

**Common side effects** effects that occur in 1-10 in 100 users

- Calcium excess if calcium intake is too high (for 1.75 mmol/l calcium only)
- High blood sugar levels
- High blood fat levels
- Weight gain

**Uncommon side effects** effects that occur in 1-10 in 1,000 users

- Lack of calcium (for 1.25 mmol/l calcium only)
- Body fluid levels that are too low, which can be identified by rapid weight loss, low blood pressure, rapid pulse
- Body fluid levels that are too high, which can be identified by presence of water in the tissues and lungs, high blood pressure, breathing difficulties
- Dizziness

**Side effects of unknown frequency** frequency cannot be estimated from the existing data

- An overactive parathyroid gland leading to possible bone disorders (for 1.25 mmol/l calcium only)

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.**

#### **Reporting side effects**

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

#### **5. HOW SHOULD THE MEDICINE BE STORED?**

**Avoid poisoning!** This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the bag and package. The expiry date refers to the last day of that month.

Do not store Balance below 4°C.

Use the ready-to-use solution immediately, within a maximum of 24 hours after mixing.

#### **6. FURTHER INFORMATION**

In addition to the active ingredients, the medicine also contains:

water for injections, hydrochloric acid, sodium hydroxide and sodium hydrogen carbonate.

**What the medicine looks like and the contents of the package:**

The solution is clear and colorless.

Balance is available in a double-chamber bag. One chamber contains an alkaline sodium lactate solution and the second chamber contains an acidic glucose-based electrolytic solution.

Balance is available in packages with the following application systems and package sizes:

<b>Safe•Lock</b>	<b>sleep•safe</b>	<b>stay•safe</b>
2 bags x 5000 ml	4 bags x 3000 ml 2 bags x 5000 ml	4 bags x 2000 ml 4 bags x 2500 ml 4 bags x 3000 ml

Not all package sizes may be marketed.

#### **License holder**

Fresenius Medical Care Israel P.B Ltd., 4 HaSheizaf St., 4366411 Raanana, Israel.

#### **Manufacturer**

Fresenius Medical Care Deutschland GmbH, Else-Kroner-Strasse 1, D- 61352, Bad Homburg, Germany.

#### **Approved in September 2022**

**Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:**

**Balance 1.5% glucose, 1.25 mmol/l calcium:**

**170-75-36170-00**

**Balance 1.5% glucose, 1.75 mmol/l calcium:**

**170-74-36171-00**

**Balance 2.3% glucose, 1.25 mmol/l calcium:**

**170-73-36172-00**

**Balance 2.3% glucose, 1.75 mmol/l calcium:**

**170-72-36173-00**

**Balance 4.25% glucose, 1.25 mmol/l calcium:**

**170-71-36174-00**

**Balance 4.25% glucose, 1.75 mmol/l calcium:**

**170-70-36175-00**