balance

2.3 % glucose

1.25 mmol/l calcium

Package leaflet: Information for the user

balance 2.3% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis

What is in this leaflet

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 of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

1. What *balance* is and what it is used for

***balance* 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. What you need to know before you use *balance*

Do not use *balance* 2.3% glucose, 1.25 mmol/l calcium
- if the level of **potassium in your blood is very low**
- if the level of **calcium in your blood is very low**
- if you have a **disorder of metabolism known as lactic acidosis**

Peritoneal dialysis treatment must not be started if you have
- **alterations in the abdominal region** such as
  – injuries or after surgery
  – burns
  – large inflammatory skin reactions
  – inflammation of the peritoneum
  – non-healing weeping wounds
  – umbilical, inguinal or diaphragmatic hernias
  – tumours in the abdomen or bowel
- 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

Warnings and precautions
Inform your doctor immediately
- if you have an **overactive parathyroid gland**. It may be necessary to take additionally calcium-containing phosphate binders and/or vitamin D.
- 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 to use a peritoneal dialysis solution with a higher calcium concentration.
- if you have **a severe loss of electrolytes (salts)** due to vomiting and/or diarrhoea
- if you have **abnormal kidneys** (polycystic kidneys)
- if you 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.
- if you 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.

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.

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, 1.25 mmol/l calcium should be used cautiously and under monitoring by your doctor.

Other medicines and *balance*
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 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 have a baby, ask your doctor for advice before taking this medicine. There are no adequate data from the use of *balance* in pregnant women or during lactation period. If you are pregnant or breast-feeding you should use *balance* **only if your doctor considers this absolutely necessary.**

Driving and using machines
balance has no or negligible influence on the ability to drive and use machines.

3. How to use *balance*

Always use this medicine 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.

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

Continuous ambulatory peritoneal dialysis (CAPD):
- **Adults:** The usual dose is 2000–3000 ml solution four times daily depending on body weight and kidney function.

  After 2-10 hours dwell time the solution is drained off.
- **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/m^2 (up to 1000 ml/m^2 overnight) body surface area four times daily.

Automated peritoneal dialysis (APD):
For this, the *sleep•safe* or the Safe•Lock system is used. Bag exchange is controlled automatically by the cycler over night.
- **Adults:** The usual prescription is 2000 ml (maximum 3000 ml) per exchange with 3-10 exchanges overnight and time on the cycler 8 to 10 hours, and at daytime one or two exchanges.
- **Children:** The volume per exchange should be 800-1000 ml/m^2 (up to 1400 ml/m^2) body surface area with 5-10 exchanges overnight.

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

Use *balance* only 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 as described.

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

The solution bag is first warmed to body temperature. This should be done by using an appropriate bag warmer. 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. 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 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 that all peel seams are completely open. ▸ Check that the solution is clear and that the bag is not leaking.

2. Preparation of the bag exchange

▸ Hang the solution bag in 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 to the drainage bag, hang the drainage bag in the lower hole of the infusion pole. ▸ Place 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 extension. The outflow starts. ▸ Position ●

4. Flush

▸ After completion of outflow flush fresh solution into the drainage bag (approx. 5 seconds). ▸ Position ●●

5. Inflow

▸ Start inflow by turning the control switch to ▸ Position ○◑●

6. Safety step

▸ Close the catheter extension 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 to 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 automated peritoneal dialysis (APD) the solution is warmed automatically by the cycler.

3000 ml *sleep•safe* system

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

2. Unroll tubing of bag.

3. Remove the protection cap.

4. Insert bag connector in free tray port of the *sleep•safe* cycler.

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

5000 and 6000 ml *sleep•safe* system

1. Preparation of the solution

▸ Check the 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. ▸ Wash your hands with an antimicrobial washing lotion. ▸ Unfold middle peel seam and 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 3000 ml *sleep•safe* system

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

During automated peritoneal dialysis (APD) the solution is warmed automatically by the cycler.

1. Preparation of the solution: see 5000 and 6000 ml *sleep•safe* system

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

3. Connect 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.

Each bag should be used only once and any unused solution remaining must be discarded.

After appropriate training, *balance* can be used independently at home. For this, it is to be ensured that all steps learnt during training as well as hygienic conditions are strictly observed when exchanging bags.

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

If you use more *balance* 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 *balance*

Try to attain the volume of dialysate prescribed for each 24-hour period in order to avoid the risk of possibly life-threatening consequences. You should check with your doctor if you are not sure.

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

4. Possible side effects

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

The following side effects may occur as a result of the peritoneal dialysis treatment in general:

very common (may affect more than 1 in 10 people):
- 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 (may affect up to 1 in 10 people):
- problems with inflow or outflow of the dialysate
- sensation of stretching or fullness of the abdomen
- shoulder pain

uncommon (may affect up to 1 in 100 people):
- diarrhoea
- constipation

very rare (may affect up to 1 in 10000 people):
- blood poisoning

not known (frequency cannot be estimated from available data):
- breathing difficulties
- feeling unwell
- encapsulating peritoneal sclerosis, possible symptoms may be abdominal pain, abdominal distension or vomiting

The following side effect may occur when *balance* is used:

very common (may affect more than 1 in 10 people):
- potassium deficiency

common (may affect up to 1 in 100 people):
- high blood sugar levels
- high blood fat levels
- weight gain

uncommon (may affect up to 1 in 100 people):
- lack of calcium
- body fluid levels too low, which can be recognised by rapid weight loss, low blood pressure, rapid pulse
- body fluid levels too high, which can be recognised by water in the tissues and lung, high blood pressure, breathing difficulties
- dizziness

not known (frequency cannot be estimated from available data):
- an overactive parathyroid gland leading to possible bone disorders

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For United Kingdom:
Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

For Malta:
www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

GB M

5. How to store *balance*

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

Do not use this medicine after the expiry date which is stated on the bag and carton after "EXP". The expiry date refers to the last day of that month.

Do not store *balance* below 4 °C.

The ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing.

6. Contents of the pack and other information

What *balance* contains

The **active substances in 1 litre of the ready-to-use solution** are:

Calcium chloride dihydrate	0.1838 g
Sodium chloride	5.640 g
Sodium (S)-lactate solution (3.925 g sodium (S)-lactate)	7.85 g
Magnesium chloride hexahydrate	0.1017 g
Glucose monohydrate (22.73 g anhydrous glucose)	25.0 g

These quantities of active substances are equivalent to: 1.25 mmol/l calcium, 134 mmol/l sodium, 0.5 mmol/l magnesium, 100.5 mmol/l chloride, 35 mmol/l lactate and 126.1 mmol/l glucose.

The other ingredients are water for injections, hydrochloric acid, sodium hydroxide and sodium hydrogen carbonate.

What *balance* looks like and contents of the pack

The solution is clear and colourless.

The theoretical osmolarity of the ready-to-use solution is 399 mOsm/l, the pH is about 7.0.

balance is available in a double-chamber bag. One chamber contains the alkaline sodium lactate solution and the other the acidic glucose-based electrolyte solution.

balance is available in the following application systems and pack sizes per carton:

stay•safe®	*sleep•safe*	Safe•Lock
4 × 2000 ml 4 × 2500 ml 4 × 3000 ml	4 × 3000 ml 2 × 5000 ml 2 × 6000 ml	2 × 5000 ml 2 × 6000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

See end of this multilingual package leaflet.

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UK, M: POM

This medicinal product is authorised in the Member States of the EEA under the following names:
Este medicamento está autorizado en los estados miembros del Espacio Económico Europeo con los siguientes nombres:
Este medicamento encontra-se autorizado nos Estados Membros do Espaço Económico Europeu (EEE) com os seguintes nomes:
Αυτό το φαρμακευτικό προϊόν έχει εγκριθεί στα Κράτη Μέλη του Ευρωπαϊκού Οικονομικού Χώρου (ΕΟΧ) με την ακόλουθη ονομασία:
Ce médicament est autorisé dans les Etats membres de l'Espace Economique Européen sous les noms suivants :
Šis zāles Eiropas Ekonomikas zonas (EEZ) dalībvalstīs ir reģistrētas ar šādiem nosaukumiem:
Šis vaistinis preparatas EEE valstybėse narėse registruotas tokiais pavadinimais:
See ravimpreparaat on saanud müügiloa Euroopa Majanduspiirkonna liikmesriikides järgmiste nimetustega:

B NL	***balance* 2,3 % glucose, 1,25 mmol/l calcium,** oplossing voor peritoneale dialyse
CZ	***balance* 2,3 % glucose, 1,25 mmol/l calcium,** roztok pro peritoneální dialýzu
D A L	***balance* 2,3 % Glucose, 1,25 mmol/l Calcium,** Peritonealdialyselösung
DK	***balance* 2,3 % glucose, 1,25 mmol/l calcium,** peritonealdialysevæske
E	***balance* 2,3 % glucosa, 1,25 mmol/l de calcio,** solución para diálisis peritoneal
EST	***balance* 2,3 % glükoos, 1,25 mmol/l kaltsium,** peritoneaaldialüüsilahus
F	**Neutravera glucose 2,3 %, calcium 1,25 mmol/l,** solution pour dialyse péritonéale
FIN	***balance* 2.3 % glukoosi, 1.25 mmol/l kalsium,** peritoneaalidialyysineste
GB M	***balance* 2.3 % glucose, 1.25 mmol/l calcium,** solution for peritoneal dialysis
GR CY	***balance* 2.3 % γλυκόζη, 1.25 mmol/l ασβέστιο,** Διάλυμα περιτοναϊκής διαπίδυσης (κάθαρσης)
H	***balance* 2,3 % glükóz, 1,25 mmol/l kalcium,** peritoneális dializáló oldat
HR	***balance* 2,3 % glukoze, 1,25 mmol/l kalcija,** otopina za peritonejsku dijalizu
I	***balance* 2,3 % glucosio, 1,25 mmol/l calcio,** soluzione per dialisi peritoneale
IS	***balance* 2,3 % glúkósi, 1,25 mmól/l kalsíum,** kviðskilunarlausn
LT	***balance* 2,3 % gliukozės, 1,25 mmol/l kalcio,** pilvaplėvės ertmės dializės tirpalas
LV	***balance* 2,3 % glikoze, 1,25 mmol/l kalcijs,** šķīdums peritoneālai dialīzei
N	***balance* 2,3 % glukose, 1,25 mmol kalsium/l,** peritonealdialysevæske
P	***balance* 2,3 % glucose, 1,25 mmol/l de cálcio,** solução para diálise peritoneal
PL	***balance* 2,3 % z 2,3 % glukozą i wapniem 1,25 mmol/l,** roztwór do dializy otrzewnowej
S	***balance* 2.3 % glucose, 1.25 mmol/l calcium,** peritonealdialysvätska
SK	***balance* 2.3 % glucose, 1.25 mmol/l calcium,** roztok na peritoneálnu dialýzu
SLO	***balance* 23 mg/ml glukoze, 1,25 mmol/l kalcija,** raztopina za peritonealno dializo

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