



PACKAGE LEAFLET

balance 1.5%, 2.3%, 4.25% glucose, 1.25 mmol/l calcium, peritoneal dialysis solution

Read all of this leaflet carefully before you start using this medicine.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist.
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What *balance* is and what it is used for
- Before you use *balance*
- How to use *balance*
- Possible side effects
- How to store *balance*
- Further information

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. Before you use *balance*

Do not use *balance* 1.5%, 2.3%, 4.25% 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 the **volume of your body fluids is too low** (4.25% glucose only)
- if you have **low blood pressure** (4.25% glucose only)

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
 - ulcers
- inflammatory bowel diseases
- intestinal obstruction
- lung diseases, particularly pneumonia
- blood poisoning caused by bacteria
- a disorder of metabolism known as lactic acidosis
- 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

Take special care with *balance*

- Inform your doctor immediately
- if you have a **severe loss of electrolytes** (salts) due to vomiting and/or diarrhoea
 - 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 **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.

Blood cleaning 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, blood cell counts, kidney function, body weight and nutritional state.

Using other medicines

- Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Because blood cleaning 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** (water tablets).
 - medicines taken by mouth that lower blood sugar levels or insulin**. Your blood sugar level should be measured regularly.

Pregnacy and breast-feeding

If you are pregnant or breast-feeding you should use *balance* **only if your doctor considers this absolutely necessary**, because there is only limited experience in these groups.

Driving and using machines

When used as prescribed *balance* does not impair your ability to drive or operate machines.

3. How to use *balance*

Always use *balance* exactly as your doctor has told you. You should 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 retention time in the peritoneal cavity.

If tension in the abdominal region occurs the volume must be reduced.

Continuous ambulatory peritoneal dialysis (CAPD):

- Adults:** the usual dose is 2000 – 2500 ml solution four times daily depending on body weight and kidney function.

Bags are exchanged over 24 hours. After 2–10 hours retention time the solution is drained off.

- Children:** The doctor will determine the volume of dialysis solution required depending on the age, height and body weight of the child.

The recommended dose is 30 – 40 ml/kg body weight.

Automatic peritoneal dialysis (APD):

Bag exchange is controlled automatically by the machine over night. For this, the *sleep+safe balance* system is used. 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® balance system for continuous ambulatory peritoneal dialysis (CAPD):

The solution bag is first warmed to body temperature. This should be done by using an appropriate heater tray. 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.

- Preparation of the solution**
 - Check the warmest 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 antiseptical 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. Roll now 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.

- 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 and place the disinfection cap into the organizer. Place catheter connector into the organizer. Disinfect your hands and remove the protection cap of the DISC. Connect catheter connector to the DISC.

3. Outflow

- Open the catheter extension clamp. The outflow starts. Position

4. Flush

- After completion of outflow fill the tube between solution bag and DISC completely with fluid by flushing fresh solution into the drainage bag (approx. 5 seconds). Position

5. Inflow

- Start inflow by turning the control switch to Position

- Close the catheter extension** by introducing the PIN into the catheter connector. Position
- Disconnection**
 - Remove protection cap from the new disinfection cap and screw it to 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 protection cap of the used disinfection cap, which is placed in the right holes of the organizer.

9. Check the drained dialysate

for clarity and weight and if the effluent is clear discard it. *sleep+safe balance* for automatic peritoneal dialysis (APD): During automatic peritoneal dialysis (APD) the solution is warmed automatically by the machine.

- 3000 ml *sleep+safe balance* system**
- Preparation of the solution:** see *stay+safe® balance* system
- Unroll tubing of bag.**
- Remove the protection cap.**
- Insert bag connector in free tray part of the *sleep+safe* caplet.**
- The bag is now ready for use with the *sleep+safe* set.**

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 "Take special care with *balance*".

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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, *balance* can cause side effects, although not everybody gets them. The following side effects occur as a result of the treatment:

- 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
- problems with inflow or outflow of the dialysate
 - diarrhoea
 - constipation
 - breathing difficulties
 - sensation of stretching or fullness of the abdomen
 - shoulder pain

The following side effect occurs when *balance* is used: **very common**, more than 1 in 10 persons treated

- potassium deficiency

Side effects of *balance* with unknown frequency are:

- lack of calcium
- an overactive parathyroid gland leading to possible bone disorders
- 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
- high blood sugar levels
- high blood fat levels
- weight gain

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store *balance*

Keep out of the reach and sight of children. Do not use *balance* after the expiry date printed on the bag and carton. Store below 25 °C. The ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing.

6. Further information

What *balance* contains

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

	<i>balance</i> 1.5% Glucose 1.25 mmol/L Calcium	<i>balance</i> 2.3% Glucose 1.25 mmol/L Calcium	<i>balance</i> 4.25% Glucose 1.25 mmol/L Calcium
Glucose monohydrate (equivalent to glucose)	16.5 g	25 g	46.75
Sodium chloride		5.640 g	
Sodium lactate (as sodium lactate solution)		3.925 g	
Calcium chloride dihydrate		0.1838 g	
Magnesium chloride hexahydrate		0.1017 g	
Theoretical osmolality	356 mosm/l	399 mosm/l	509 mosm/l

	<i>balance</i> 1.5% Glucose 1.25 mmol/L Calcium	<i>balance</i> 2.3% Glucose 1.25 mmol/L Calcium	<i>balance</i> 4.25% Glucose 1.25 mmol/L Calcium
Glucose	83.2 mmol/l	126.1 mmol/l	235.8 mmol/l
Sodium		134 mmol/l	
Calcium		1.25 mmol/l	
Magnesium		0.5 mmol/l	
Chloride		100.5 mmol/l	
Lactate		35 mmol/l	

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

What *balance* looks like and contents of the pack
balance is a solution for peritoneal dialysis. The solution is clear and colourless. 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:

<i>stay+safe® balance</i>	<i>sleep+safe balance</i>
6 x 1500 ml 4 x 2000 ml 4 x 2500 ml	4 x 3000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Medical Care Deutschland GmbH, 61346 Bad Homburg v.d.H., Germany

Manufacturer
Fresenius Medical Care Japan K.K., Buzen Plant, 92-7 Oaza Kaimo, Buzen-shi, Fukuoka Prefecture, Japan

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費森尤斯醫葯用品有限公司 (Fresenius Medical Care)

包裝說明書

均衡腹透透析液 1.5%、2.3%、4.25% 葡萄糖、1.25 mmol/l 鈣

balance 1.5%, 2.3 % and 4.25% glucose, 1.25 mmol/l calcium, peritoneal dialysis solution

- 使用說明書**，請先仔細閱讀此說明書。
- 請保留此說明書，以便日後有需要時參閱。
- 如果您有任何疑問，請向醫師或藥劑師查詢。
- 此藥物為您的處方藥。即使症狀相同，也可能會對他人造成傷害。
- 如果副作用加劇，或者您發現任何本說明書中未列出的副作用，請告知醫師或藥劑師。

- 準備均衡腹透透析液**
 - 檢查加熱後的溶液袋（標籤、有效期、溶液清澈度、溶液袋和外包裝沒有破損、封口完好無損）。→將溶液袋放在穩固平面上。→打開溶液袋的外包裝和消毒蓋包裝。→使用抗菌洗手液清潔雙手。→將溶液袋（置於外包裝中）從邊緣處向上捲起，直至中間的接縫打開。兩個袋裝的溶液會自動混合。→將溶液袋從上邊緣處向上捲，直到中间的三角形的封蓋完全開啟。→確認所有的封蓋完全開啟。→確保溶液清澈且溶液袋沒有洩漏。

- 什麼是您均衡腹透透析液及其作用**
 - 均衡腹透透析液可透過腹膜為患有末期慢性腎衰竭的患者洗血。這種洗血方式稱為腹透透析。

- 使用均衡腹透透析液之前**
 - 如果出現以下情況，請勿使用均衡腹透透析液 1.5%、2.3%、4.25% 葡萄糖、1.25 mmol/l 鈣：
 - 血液中的鉀含量非常低
 - 血液中的鎂含量非常低
 - 體液滲透壓低（此點注意事項僅限於使用 4.25% 葡萄糖系列的病人）
 - 低血鈣症（此點注意事項僅限於使用 4.25% 葡萄糖系列的病人）

如果您出現以下症狀，請勿接受腹透透析治療：

- 腹部出現以下異常狀況
 - 受傷或術後
 - 潰瘍
 - 大面積皮膚發炎
 - 腹膜炎
 - 流血傷口無法癒合
 - 臍部、腹腔溝或隔膜疝氣
 - 潰瘍
 - 腸道炎症
 - 腸道阻塞
 - 肺部疾病，尤其是肺炎
 - 由細菌導致的血中毒
 - 因乳酸性酸中毒所造成的代謝性紊亂
 - 血脂極高
 - 尿道問題產生的血液中毒，無法透過洗血治療
 - 嚴重營養不良和體重減輕，尤其是無法攝入足夠含有蛋白質的食物

謹慎使用均衡腹透透析液
如出現以下情況，請立即通知您的醫師：

- 嘔吐和/或腹瀉
- 嚴重失調
- 副甲狀腺亢進，可能需額外服用含鈣磷鹽結晶劑和/或維他命 D。
- 體內鈣濃度低，可能需額外服用含鈣磷鹽結晶劑和/或維他命 D，或者服用含鈣濃度更高的腹透透析溶液。
- 腎臟異常（多尿癆）
- 藥水袋和 *sleep+safe* 管組皆放回妥善等候使用。

洗血可能會導致**蛋白質和水溶性維他命流失**。建議您保持均衡膳食或服用營養補充劑，以避免營養不良。

您的醫生會檢查您的電解質（鹽分）平衡、血細胞數量、腎臟功能、體重和營養狀況。

服用其他藥物

如果您正在服用或最近服用過任何其他藥物（包括非處方藥），請告知您的醫師。

- 如果您將過多的均衡腹透透析液注入腹腔腔，可以將超出的量排出。如果您使用過多的溶液袋，請與您的醫生聯絡，因為過量使用可能會導致液體和/或電解質流失。

增加排尿的藥物（利尿劑）

- 降低血糖水平或胰島素的口服藥物**。您應該定期檢查血糖水平。

懷孕和哺乳期間

如果您已懷孕或處於哺乳期，您只應在醫師認為**確有必要**的情況下方可使用此均衡腹透透析液，因為此類人群的使用案例極為有限。

駕駛和使用機器

均衡腹透透析液不會影響您開車或操作機器的能力。

- 如何使均衡腹透透析液**
 - 使用均衡腹透透析液時應始終嚴格遵循醫囑。如果您不確定如何使，請向醫師/藥劑師查詢。
 - 您的醫師會決定使用方法、時間長度和次數，以及腹腔腔中的所需溶液容量和滯留時間。
 - 如果您腹部感覺不適，則應減少使用量。

- 連續可活動性腹透透析 (CAPD)：**
 - 成人：一般劑量為一次 2000 - 2500 ml，每日四次，視乎體重和腎臟功能而異。

在24小時內完成藥水袋的交換。在腹腔內停留 2 - 10 小時後將透析液排出。

兒童：醫師會根據兒童的年齡、身高和體重決定所需的透析液容量。

建議劑量為每公升體重 30 - 40 ml。

自動腹透透析 (APD)：
由於機器會整晚自動更換透析袋，因此適用於 *sleep+safe balance* 系統。

僅在腹膜腔使用均衡腹透透析液

僅在腹透透析液清澈及溶液袋未破損的情況下使用均衡腹透透析液。雙室溶液袋中存有腹透透析液，使用均衡腹透透析液之前必須按照指示混合兩個袋室。

- 處理說明**
- 連續可活動性腹透透析 (CAPD) 專用 *stay+safe® balance* 系統**
 - 首次加熱時，將溶液袋加熱至攝溫。應使用合適的加熱托盤進行加熱。起始溫度為 22°C 的 2000 ml 袋的加熱時間約為 120 分鐘。詳情請參閱溶液袋加熱器的操作說明。不可使用微波爐加熱溶液袋，以免發生局部過熱風險。加熱均衡溶液之後即可開始更換溶液袋。

- 準備均衡腹透透析液**
 - 檢查加熱後的溶液袋（標籤、有效期、溶液清澈度、溶液袋和外包裝沒有破損、封口完好無損）。→將溶液袋放在穩固平面上。→打開溶液袋的外包裝和消毒蓋包裝。→使用抗菌洗手液清潔雙手。→將溶液袋（置於外包裝中）從邊緣處向上捲起，直至中間的接縫打開。兩個袋裝的溶液會自動混合。→將溶液袋從上邊緣處向上捲，直到中间的三角形的封蓋完全開啟。→確認所有的封蓋完全開啟。→確保溶液清澈且溶液袋沒有洩漏。

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 - 受傷或術後
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 - 大面積皮膚發炎
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 - 肺部疾病，尤其是肺炎
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如果您出現以下症狀，請勿接受腹透透析治療：

自動腹透透析 (APD) 的 *sleep+safe balance* 系統：
由於機器會整晚自動更換透析袋，因此適用於 *sleep+safe balance* 系統。

- 3000 ml *sleep+safe balance* 系統**
- 準備均衡腹透透析液**
 - 檢查加熱後的溶液袋（標籤、有效期、溶液清澈度、溶液袋和外包裝沒有破損、封口完好無損）。→將溶液袋放在穩固平面上。→打開溶液袋的外包裝和消毒蓋包裝。→使用抗菌洗手液清潔雙手。→將溶液袋（置於外包裝中）從邊緣處向上捲起，直至中間的接縫打開。兩個袋裝的溶液會自動混合。→將溶液袋從上邊緣處向上捲，直到中间的三角形的封蓋完全開啟。→確認所有的封蓋完全開啟。→確保溶液清澈且溶液袋沒有洩漏。

洗血可能會導致**蛋白質和水溶性維他命流失**。建議您保持均衡膳食或服用營養補充劑，以避免營養不良。

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增加排尿的藥物（利尿劑）

降低血糖水平或胰島素的口服藥物。您應該定期檢查血糖水平。

懷孕和哺乳期間

如果您已懷孕或處於哺乳期，您只應在醫師認為**確有必要**的情況下方可使用此均衡腹透透析液，因為此類人群的使用案例極為有限。

駕駛和使用機器

均衡腹透透析液不會影響您開車或操作機器的能力。

- 如何使均衡腹透透析液**
 - 使用均衡腹透透析液時應始終嚴格遵循醫囑。如果您不確定如何使，請向醫師/藥劑師查詢。
 - 您的醫師會決定使用方法、時間長度和次數，以及腹腔腔中的所需溶液容量和滯留時間。
 - 如果您腹部感覺不適，則應減少使用量。

- 連續可活動性腹透透析 (CAPD)：**
 - 成人：一般劑量為一次 2000 - 2500 ml，每日四次，視乎體重和腎臟功能而異。

在24小時內完成藥水袋的交換。在腹腔內停留 2 - 10 小時後將透析液排出。

兒童：醫師會根據兒童的年齡、身高和體重決定所需的透析液容量。

建議劑量為每公升體重 30 - 40 ml。

- 的人士身上
- 缺鈣
- 使用均衡腹透透析液的無法確定的頻率副作用包括：
 - 缺鈣
 - 副甲狀腺亢進，可能需額外服用含鈣磷鹽結晶劑和/或維他命 D。</



PACKAGE LEAFLET

balance 1.5%, 2.3%, 4.25% glucose, 1.75 mmol/l calcium, peritoneal dialysis solution

<p>Read all of this leaflet carefully before you start using this medicine.</p> <ul style="list-style-type: none">Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

- What *balance* is and what it is used for
- Before you use *balance*
- How to use *balance*
- Possible side effects
- How to store *balance*
- Further information

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. Before you use *balance*

Do not use *balance* 1.5%, 2.3%, 4.25% glucose, 1.75 mmol/l calcium if

- if the level of **potassium in your blood is very low**
- if the level of **calcium in your blood is very high**
- if the **volume of your body fluids is too low** (4.25% glucose only)
- if you have **low blood pressure** (4.25% glucose only)

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
 - ulcers
- inflammatory bowel diseases
- intestinal obstruction
- lung diseases, particularly pneumonia
- blood poisoning caused by bacteria
- a disorder of metabolism known as lactic acidosis
- 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
- Take special care with *balance***

Inform your doctor immediately

- 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.
- Blood cleaning 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, blood cell counts, kidney function, body weight and nutritional state.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Because blood cleaning 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** (water tablets).
 - medicines taken by mouth that lower blood sugar levels or insulin**. Your blood sugar level should be measured regularly.
- Pregnancy and breast-feeding**
- If you are pregnant or breast-feeding you should use *balance* **only if your doctor considers this absolutely necessary**, because there is only limited experience in these groups.

Driving and using machines

When used as prescribed *balance* does not impair your ability to drive or operate machines.

3. How to use *balance*

Always use *balance* exactly as your doctor has told you. You should 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 retention time in the peritoneal cavity. If tension in the abdominal region occurs the volume must be reduced.
Continuous ambulatory peritoneal dialysis (CAPD):

- Adults:** the usual dose is 2000 – 2500 ml solution four times daily depending on body weight and kidney function. Bags are exchanged over 24 hours. After 2 –10 hours retention time the solution is drained off.
- Children:** The doctor will determine the volume of dialysis solution required depending on the age, height and body weight of the child. The recommended dose is 30 –40 ml/kg body weight.

- body fluid levels too high, which can be recognised by water in the tissues and lung, high blood pressure, breathing difficulties
- high blood sugar levels
- high blood fat levels
- weight gain

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store *balance*

Do not use *balance* after the expiry date printed on the bag and carton. Store below 25 °C. The ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing.

6. Further information

What *balance* contains

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

	<i>balance</i> 1.5% Glucose 1,75 mmol/L Calcium	<i>balance</i> 2.3% Glucose 1,75 mmol/L Calcium	<i>balance</i> 4.25% Glucose 1,75 mmol/L Calcium
Glucose monohydrate	16,5 g	25 g	46,75
(equivalent to glucose)	15 g	22,73 g	42,5 g
Sodium chloride		5,640 g	
Sodium lactate (as sodium lactate solution)		3,925 g	
Calcium chloride dihydrate		0,2573 g	
Magnesium chloride hexahydrate		0,1017 g	
Theoretical osmolality	358 mosm/l	401 mosm/l	511 mosm/l

These quantities of active substances are equivalent to:

	<i>balance</i> 1.5% Glucose 1,75 mmol/L Calcium	<i>balance</i> 2.3% Glucose 1,75 mmol/L Calcium	<i>balance</i> 4.25% Glucose 1,75 mmol/L Calcium
Glucose	83,2 mmol/l	126,1 mmol/l	235,8 mmol/l
Sodium		134 mmol/l	
Calcium		1,75 mmol/l	
Magnesium		0,5 mmol/l	
Chloride		101,5 mmol/l	
Lactate		35 mmol/l	

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

What *balance* looks like and contents of the pack
balance is a solution for peritoneal dialysis. The solution is clear and colourless. 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:

<i>stay+safe® balance</i>	<i>sleep+safe balance</i>
6 x 1500 ml 4 x 2000 ml 4 x 2500 ml	4 x 3000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Medical Care Deutschland GmbH, 61346 Bad Homburg v.d.H., Germany

Manufacturer
Fresenius Medical Care Japan K.K., Buzen Plant, 92-7 Oaza Kaimo, Buzen-shi, Fukuoka Prefecture, Japan

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

This leaflet was last revised in September 2013

balance 1.5, 2.3, 4.25 % glucose, 1.75 mmol/l calcium: 0875162/01, 0875163/01, 0875164/01 (12/2010)

費森尤斯醫葯用品有限公司 (Fresenius Medical Care)

包裝說明書

均衡腹膜透析液 1.5%、2.3%、4.25% 葡萄糖、1.75 mmol/l 鈣
balance 1.5%, 2.3% and 4.25% glucose, 1.75 mmol/l calcium, peritoneal dialysis solution

均在腹膜腔使用均衡腹膜透析液。僅在腹膜透析液清液及溶液袋未破損的情況下使用均衡腹膜透析液。雙室溶液袋中存有腹膜透析液，使用前均衡腹膜透析液之前必須按照指示混合兩個袋室。

說明書內容摘要：

- 請保留此說明書，以便日後有需要時參閱。
- 如果您有任何疑問，請向醫師或藥劑師查詢。
- 此藥物為您的處方藥。請勿轉贈他人，即使症狀相同，也可能會對他人造成傷害。

- 如果副作用加劇，或者您發現任何本說明書中未列出的副作用，請告知醫師或藥劑師。

處理說明
連續可活動性腹膜透析 (CAPD) 專用 *stay+safe® balance* 系統
首次加熱時，將溶液袋加熱至攝溫。應使用合適的加熱托盤進行加熱。起始溫度為 22°C 的 2000 ml 袋的加熱時間約為 120 分鐘。詳情請參閱溶液袋加熱器的操作說明。不可使用微波爐加熱溶液袋，以免發生局部過熱風險。加熱均衝液之後即可開始更換溶液袋。

說明書內容摘要：

- 什麼是均衡腹膜透析液及其作用
- 如何使用均衡腹膜透析液之前
- 如何使均衡腹膜透析液作用
- 可能發生的副作用
- 如何儲存均衡腹膜透析液
- 更詳盡的資訊

1. 什麼是均衡腹膜透析液及其作用

均衡腹膜透析液可透過腹膜為患有末期慢性腎衰竭的患者洗血。這種洗血方式稱為腹膜透析。

2. 使用均衡腹膜透析液之前

如果出現以下情況，**請勿使用均衡腹膜透析液 1.5%、2.3%、4.25% 葡萄糖、1.75 mmol/l 鈣**：

- 血液中的鉀含量非常低**
- 血液中的鈣含量非常高**
- 體液含過低鈣**（此點注意事項僅限於使用 4.25% 葡萄糖系列的病人）
- 低血壓**（此點注意事項僅限於使用 4.25% 葡萄糖系列的病人）

如果您出現以下症狀，請勿接受腹膜透析治療：

- 腹部出現以下異常狀況
 - 受傷或術後
 - 潰瘍
 - 大面積皮膚發炎
 - 腹膜炎
- 流血傷口無法癒合
- 臍部、腹腔溝或隔膜疝氣
- 潰瘍
- 腸道炎症
- 腸道阻塞
- 肺部疾病，尤其是肺炎
- 由細菌導致的血中毒
- 因脂酸性酸中毒所造成的代謝性紊亂
- 脂肪腫高
- 尿道問題產生的血尿或血毒，無法透過洗血治療
- 嚴重營養不良和體重減輕，尤其是無法攝入足夠含有蛋白質的食物

謹慎使用均衡腹膜透析液
如出現以下情況，請立即通知您的醫師：

- 嘔吐和/或腹瀉或電解質（鹽分）嚴重流失
- 腎臟異常（多寡尿）
- 腹膜炎，可透過薄濺透析液和/或腹部疼痛辨認。請向醫師出示代謝透析液的袋子

洗血可能會導致**蛋白質和水溶性維他命流失**。建議您保持均衡膳食或服用營養補充劑，以避免營養不良。

您的醫生會檢查您的電解質（鹽分）平衡、血細胞數量、腎臟功能、體重和營養狀況。

服用其他藥物

如果您正在服用或最近服用過任何其他藥物（包括非處方藥），請告知您的醫師。

- 心臟衰竭藥物**，如地高辛，您的醫師會檢查您血液中的地高辛量，必要時會採取恰當的措施。
- 影響鈣質水平的藥物**，如鈣鈣或維他命 D 的藥物。
- 增加排尿的藥物**（利尿劑）。

降低血糖水平或糖尿病的口服藥物。您應該定期檢查血糖水平。

<i>stay+safe® balance</i>	<i>sleep+safe balance</i>
6 x 1500 ml 4 x 2000 ml 4 x 2500 ml	4 x 3000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Fresenius Medical Care Deutschland GmbH, 61346 Bad Homburg v.d.H., Germany

Manufacturer
Fresenius Medical Care Japan K.K., Buzen Plant, 92-7 Oaza Kaimo, Buzen-shi, Fukuoka Prefecture, Japan

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

This leaflet was last revised in September 2013

balance 1.5, 2.3, 4.25 % glucose, 1.75 mmol/l calcium: 0875162/01, 0875163/01, 0875164/01 (12/2010)

自動腹膜透析 (APD)：

由於機器會整晚自動更換透析液，因此會啟用 *sleep+safe balance* 系統。

均在腹膜腔使用均衡腹膜透析液。僅在腹膜透析液清液及溶液袋未破損的情況下使用均衡腹膜透析液。雙室溶液袋中存有腹膜透析液，使用前均衡腹膜透析液之前必須按照指示混合兩個袋室。

說明書內容摘要：

- 請保留此說明書，以便日後有需要時參閱。
- 如果您有任何疑問，請向醫師或藥劑師查詢。
- 此藥物為您的處方藥。請勿轉贈他人，即使症狀相同，也可能會對他人造成傷害。
- 如果副作用加劇，或者您發現任何本說明書中未列出的副作用，請告知醫師或藥劑師。

處理說明
連續可活動性腹膜透析 (CAPD) 專用 *stay+safe® balance* 系統
首次加熱時，將溶液袋加熱至攝溫。應使用合適的加熱托盤進行加熱。起始溫度為 22°C 的 2000 ml 袋的加熱時間約為 120 分鐘。詳情請參閱溶液袋加熱器的操作說明。不可使用微波爐加熱溶液袋，以免發生局部過熱風險。加熱均衝液之後即可開始更換溶液袋。

說明書內容摘要：

- 什麼是均衡腹膜透析液及其作用
- 如何使用均衡腹膜透析液之前
- 如何使均衡腹膜透析液作用
- 可能發生的副作用
- 如何儲存均衡腹膜透析液
- 更詳盡的資訊

1. 準備均衡腹膜透析液
一檢查加熱後的溶液袋（標籤、有效期、溶液清濁度、溶液袋和外包裝沒有破損、封口完好無損）。→將溶液袋放在穩固平面上。→打開溶液袋的外包裝和消毒蓋包裝。→使用750ml 洗手液清潔雙手。→將溶液袋（置於外包裝中）從邊緣處向上捲起，直至中間的接頭被打開。兩個袋室裝的溶液會自動混合。→將溶液袋從上邊緣處向上捲，直到下面的三角形的封蓋完全開啟。→確認所有的封蓋完全開啟。→確保溶液清液且溶液袋沒有洩漏。

2. 準備換液
→把藥水袋掛在點滴架上，解開盤繞的藥水袋輸液管，將 DISC 放入固定器內。解開盤繞的引流袋輸液管後，將引流袋掛在點滴架下面的掛勾，再將新的消毒蓋置入固定器內。→將腹膜透析導管延長管接頭置入固定器→→消毒您的雙手，將 DISC 的保護帽移除。→ 將腹膜透析導管延長管接頭與換液到 DISC。

3. 引流
→打開導管延長管上的管夾。開始引流。→ DISC 上前頭定位在 “●”

4. 沖洗
→ 引流完成後，藉由新鮮藥水袋裝水沖洗藥水袋至DISC之間的管路到引流袋中(約5秒)。→ DISC 上前頭定位在 “●●”

5. 灌入
→ 轉動 DISC 上前頭定位在 “○●●” 開始灌入新鮮透析液到腹腔內。

6. 安全步驟
→ 藉由 PIN 自動射出，封閉導管延長管接頭。
→DISC 上前頭定位在 “●●●●”

7. 分離
→ 從新的消毒帽取下保護蓋並鎖在舊的消毒帽上。從 DISC 上取下導管延長管接頭，將導管延長管接頭銜接上新的消毒帽鎖緊。

8. 關閉 DISC。
→ 用放置於 DISC 右孔蓋的消毒帽保護蓋末端關閉DISC。

9. 檢查已排出透析液的清濁度及秤重，如果排出血是清澈的便可以倒掉。

自動腹膜透析 (APD) 的 *sleep+safe balance* 系統：
在自動腹膜透析 (APD) 過程中，透析液是在機器內自動加熱。

(A) 3000 ml *sleep+safe balance* 系統

- 透析液的準備：**請參考 *stay+safe® balance* 系統
- 解開腹繞的輸液管。**
- 移除保護蓋帽。**
- 將藥水袋接頭置入 *sleep+safe* 管組平壓。**
- 藥水袋和 *sleep+safe* 管組皆放置妥當等候使用。**

每個溶液袋只可使用一次，任何剩餘的未使用均衡腹膜透析液必須倒掉。接受適當訓練後，可以在家自行使用均衡腹膜透析液。在家使用時，更換溶液袋時應嚴格遵守培訓期間學習到的所有步驟以及衛生條件。

請務必檢查排出透析液的清濁度。詳情請參閱第 2 部分「謹慎使用均衡腹膜透析液」。

<i>stay+safe® balance</i>	<i>sleep+safe balance</i>
6 X 1500 ml 4 X 2000 ml 4 X 2500 ml	4 X 3000 ml

並非所有包裝均有推廣銷售。

持牌推廣銷售商
Fresenius Medical Care Deutschland GmbH, 61346 Bad Homburg v.d.H., Germany

製造商
Fresenius Medical Care Japan K.K., Buzen Plant, 92-7 Oaza Kaimo, Buzen-shi, Fukuoka Prefecture, Japan

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

This leaflet was last revised in September 2013

balance 1.5, 2.3, 4.25 % glucose, 1.75 mmol/l calcium: 0875162/01, 0875163/01, 0875164/01 (12/2010)

的人士身上

- 缺鈣

- 使用均衡腹膜透析液的頻率無法確定的副作用包括：
 - 如果攝取過多鈣質，則鈣含量會過高
 - 體液過低，症狀為體重快速減輕、低血壓和脈搏加速
 - 體液過高，症狀為組織和肺部積水、高血壓和呼吸困難
 - 高血糖
 - 高血壓
 - 體重增加

如果副作用加劇，或者您發現任何本說明書中未列出的副作用，請告知醫師或藥劑師。

5. 如何儲存均衡腹膜透析液

請置於兒童無法觸及或看到的方。請將均溶液袋和包裝箱上標示的有效日期後使用均衡腹膜透析液。請勿將均衡腹膜透析液儲存在 25°C 以下的地方。即用型的均衡腹膜透析液應立即使用，混合之後應在 24 小時內使用。

6. 更詳盡的資訊

均衡腹膜透析液：

每公升即用型均衡腹膜透析液所含的主要成份為：

	均衡腹膜透析液 1.5% 葡萄糖、1.75 mmol/l 鈣	均衡腹膜透析液 2.3% 葡萄糖、1.75 mmol/l 鈣	均衡腹膜透析液 4.25% 葡萄糖、1.75 mmol/l 鈣
葡萄糖 (1 份水)	16,5 g	25 g	46,75
(相當於無水性葡萄糖)	15 g	22,73 g	42,5 g
氯化鈣		5,640 g	
乳酸鈣 (為乳酸鈣溶液)		3,925 g	
氯化鈣 (2 份水)		0,2573 g	
氯化鈣 (6 份水)		0,1017 g	
理論滲透壓	358 mosm/l	401 mosm/l	511 mosm/l

此等含量的主要成份相當於：

	均衡腹膜透析液 1.5% 葡萄糖、1.75 mmol/l 鈣	均衡腹膜透析液 2.3% 葡萄糖、1.75 mmol/l 鈣	均衡腹膜透析液 4.25% 葡萄糖、1.75 mmol/l 鈣
葡萄糖	83,2 mmol/l	126,1 mmol/l	235,8 mmol/l
鈉		134 mmol/l	
鈣		1,75 mmol/l	
鎂		0,5 mmol/l	
氯化物		101,5 mmol/l	
乳酸鹽		35 mmol/l	

均衡腹膜透析液中的其他成分為水分，用於注射劑、鹽酸、氫氧化鈉和碳酸鈉鹽。

均衡腹膜透析液的外觀和包裝附屬品
均衡腹膜透析液是用於腹膜透析的溶液。溶液為無色透明。pH 值約為 7.0。溶液裝於雙室袋中，一個袋室裝有酸性乳酸鹽鈉溶液，另一個袋室裝有酸性葡萄糖電解質溶液。每盒溶液備有以下使用系統和包裝：

<i>stay+safe® balance</i>	<i>sleep+safe balance</i>
6 X 1500 ml 4 X 2000 ml 4 X 2500 ml	4 X 3000 ml

並非所有包裝均有推廣銷售。

持牌推廣銷售商
Fresenius Medical Care Deutschland GmbH, 61346 Bad Homburg v.d.H., Germany

製造商
Fresenius Medical Care Japan K.K., Buzen Plant, 92-7 Oaza Kaimo, Buzen-shi, Fukuoka Prefecture, Japan

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

This leaflet was last revised in September 2013

balance 1.5, 2.3, 4.25 % glucose, 1.75 mmol/l 鈣：0875162/01, 0875163/01, 0875164/01 (12/2010)

세이피디 2,3,4 밸런스 복강투석액	전문의약품			
(원료약품 및 그 분량)				
<p>Calcium 1.75mmol/L</p> <p>각 1L 중</p> <p>세이피디2 밸런스세이피디3 밸런스세이피디4 밸런스복강투석액</p>				
A액	염화나트륨 (EP) 11.279g 염화칼슘이수화물 (EP) 0.1545g 염화나트륨수소화물 (EP) 0.2033g 염산, 수산화나트륨, 주사용수	11.279g 0.1545g 0.2033g 33g	11.279g 0.1545g 0.2033g 93.5g	11.279g 0.1545g 0.2033g 50g
B액	락트산나트륨50%(EP) 락트산나트륨, 주사용수	15.69g	15.69g	15.69g
나트륨으로서 함으로서 마그네슘으로서 락트산으로서 염산으로서 락트산수소염으로서	134.0mmol 1.75mmol 0.5mmol 35.0mmol 101.5mmol 15.0g 2.0mmol	134.0mmol 1.75mmol 0.5mmol 35.0mmol 101.5mmol 4.25g 2.0mmol	134.0mmol 1.75mmol 0.5mmol 35.0mmol 101.5mmol 4.25g 2.0mmol	134.0mmol 1.75mmol 0.5mmol 35.0mmol 101.5mmol 2.73g 2.0mmol