

## **Abbreviated Prescribing Information**

*balance 1.5% glucose, 1.75 mmol/l calcium*, solution for peritoneal dialysis  
*balance 2.3% glucose, 1.75 mmol/l calcium*, solution for peritoneal dialysis  
*balance 4.25% glucose, 1.75 mmol/l calcium*, solution for peritoneal dialysis  
*balance 1.5% glucose, 1.25 mmol/l calcium*, solution for peritoneal dialysis  
*balance 2.3% glucose, 1.25 mmol/l calcium*, solution for peritoneal dialysis  
*balance 4.25% glucose, 1.25 mmol/l calcium*, solution for peritoneal dialysis

These solutions are delivered in a double chamber bag. One chamber contains the alkaline lactate solution, the other chamber contains the acidic glucose-based electrolyte solution. Mixing of both solutions by opening the middle seam between the two chambers results in the neutral ready-to-use solution.

### **Composition:**

#### **1 litre of the neutral ready-to-use solution contains:**

*balance 1.5% glucose, 1.75 mmol/l calcium*: calcium chloride dihydrate 0.2573 g, sodium chloride 5.640 g, sodium (S)-lactate solution 7.85 g (sodium (S)-lactate 3.925 g), magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 16.5 g (glucose 15.0 g)

*balance 2.3% glucose, 1.75 mmol/l calcium*: calcium chloride dihydrate 0.2573 g, sodium chloride 5.640 g, sodium (S)-lactate solution 7.85 g (sodium (S)-lactate 3.925 g), magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 25.0 g (glucose 22.73 g)

*balance 4.25% glucose, 1.75 mmol/l calcium*: calcium chloride dihydrate 0.2573 g, sodium chloride 5.640 g, sodium (S)-lactate solution 7.85 g (sodium (S)-lactate 3.925 g), magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 46.75 g (glucose 42.5 g)

*balance 1.5% glucose, 1.25 mmol/l calcium*: calcium chloride dihydrate 0.1838 g, sodium chloride 5.640 g, sodium (S)-lactate solution 7.85 g (sodium (S)-lactate 3.925 g), magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 16.5 g (glucose 15.0 g)

*balance 2.3% glucose, 1.25 mmol/l calcium*: calcium chloride dihydrate 0.1838 g, sodium chloride 5.640 g, sodium (S)-lactate solution 7.85 g (sodium (S)-lactate 3.925 g), magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 25.0 g (glucose 22.73 g)

*balance 4.25% glucose, 1.25 mmol/l calcium*: calcium chloride dihydrate 0.1838 g, sodium chloride 5.640 g, sodium (S)-lactate solution 7.85 g (sodium (S)-lactate 3.925 g), magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 46.75 g (glucose 42.5 g)

### **Excipients:**

Water for injections, hydrochloric acid, sodium hydroxide, sodium hydrogen carbonate.

### **Indications:**

End-stage (decompensated) chronic renal failure of any origin which can be treated with peritoneal dialysis.

### **Contraindications:**

#### **Solution related:**

Solutions with 1.75 mmol/l calcium: Lactic acidosis, severe hypokalaemia and severe hypercalcaemia.  
Solutions with 1.25 mmol/l calcium: Lactic acidosis, severe hypokalaemia and severe hypocalcaemia.  
Solutions with 4.25% glucose: Additionally hypovolaemia and arterial hypotension.

#### **Treatment related:**

Recent abdominal surgery or injury, a history of abdominal operations with fibrous adhesions, severe abdominal burns, bowel perforation; extensive inflammatory conditions of the abdominal skin (dermatitis); inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis); peritonitis; internal or external abdominal fistula; umbilical, inguinal or other abdominal hernia; intra-abdominal tumours; ileus; pulmonary disease (especially pneumonia); sepsis; extreme hyperlipidaemia; rare cases of uraemia, which cannot be managed by peritoneal dialysis; cachexia and severe weight loss, particularly in cases in where ingestion of adequate protein is not guaranteed; patients who are physically or mentally incapable of performing PD as instructed by the physician.

**Undesirable effects:****Solution specific:**

Electrolyte disturbances, e.g. hypokalaemia, additionally hypocalcaemia for solutions containing 1.25 mmol/l calcium respectively hypercalcaemia in combination with an increased calcium uptake for solutions containing 1.75 mmol/l calcium; disturbances in hydration, e.g. dehydration, indicated by a rapid decrease in body weight, hypotension, dizziness and/or tachycardia, or overhydration indicated by a rapid increase in body weight, oedema, hypertension and/or dyspnoea; increased blood sugar levels; hyperlipidaemia; increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution. Secondary hyperparathyroidism with potential disturbances of the bone metabolism for solutions containing 1.25 mmol/l calcium.

**For peritoneal dialysis in general:**

Peritonitis, indicated by cloudy effluent, later abdominal pain, fever, and general malaise or, in very rare cases, sepsis may develop; skin exit site or tunnel infection of the catheter indicated by redness, oedema, pain, exudations or crusts; in- and outflow disturbances of the dialysis solution, diarrhoea or constipation, dyspnoea caused by the elevated diaphragm; hernia; abdominal distension and sensation of fullness; shoulder pain.

Possibly balance or not all strengths of balance are registered or marketed in your country.

**Date:** November 2016

**Fresenius Medical Care Deutschland GmbH**

Else-Kröner-Straße 1, 61352 Bad Homburg v.d.H., Germany