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 specific:

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, 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; abdominal fistula; 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 where ingestion of adequate protein is not guaranteed; physical or mental disability to perform peritoneal dialysis.
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.

Treatment related:
Peritonitis, indicated by cloudy effluent, later abdominal pain, fever, and general malaise or, in very rare cases, sepsis; 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, encapsulating peritoneal sclerosis; 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: January 2020

Fresenius Medical Care Deutschland GmbH
Else-Kröner-Straße 1, 61352 Bad Homburg v.d.H., Germany
Abbreviated Prescribing Information

**bicaVera 1.5 % Glucose, 1.75 mmol/l Calcium**, Solution for peritoneal dialysis
**bicaVera 2.3 % Glucose, 1.75 mmol/l Calcium**, Solution for peritoneal dialysis
**bicaVera 4.25 % Glucose, 1.75 mmol/l Calcium**, Solution for peritoneal dialysis
**bicaVera 1.5 % Glucose, 1.25 mmol/l Calcium**, Solution for peritoneal dialysis
**bicaVera 2.3 % Glucose, 1.25 mmol/l Calcium**, Solution for peritoneal dialysis
**bicaVera 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 hydrogen carbonate solution, the other chamber contains the acidic glucose-based electrolyte solution. Mixing of both solutions by opening the median seam between the two chambers results in the ready-to-use solution.

**Composition:**

1 litre of the ready-to-use solution contains:

**bicaVera 1.5 % Glucose, 1.75 mmol/l Calcium**: calcium chloride dihydrate 0.2573 g, sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 16.5 g (glucose 15.0 g)

**bicaVera 2.3 % Glucose, 1.75 mmol/l Calcium**: calcium chloride dihydrate 0.2573 g, sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 25.0 g (glucose 22.73 g)

**bicaVera 4.25 % Glucose, 1.75 mmol/l Calcium**: calcium chloride dihydrate 0.2573 g, sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 46.75 g (glucose 42.5 g)

**bicaVera 1.5 % Glucose, 1.25 mmol/l Calcium**: calcium chloride dihydrate 0.1838 g, sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 16.5 g (glucose 15.0 g)

**bicaVera 2.3 % Glucose, 1.25 mmol/l Calcium**: calcium chloride dihydrate 0.1838 g, sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 25.0 g (glucose 22.73 g)

**bicaVera 4.25 % Glucose, 1.25 mmol/l Calcium**: calcium chloride dihydrate 0.1838 g, sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 46.75 g (glucose 42.5 g)

**Excipients**

Hydrochloric acid, sodium hydroxide, carbon dioxide, water for injections

**Indications:**

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

**Contraindications:**

- **Solution specific:** Solutions with 1.75 mmol/l calcium: Severe hypokalaemia and severe hypercalcaemia.
- Solutions with 1.25 mmol/l calcium: Severe hypokalaemia and severe hypocalcaemia.
- Solutions with 2.3%/4.25% glucose: additionally hypovolaemia and arterial hypotension.

**Treatment related:**

Recent abdominal surgery or injury, 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); localized peritonitis; abdominal fistula; 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 where ingestion of adequate protein is not guaranteed; physical or mental disability to perform peritoneal dialysis.
**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.

**Treatment related:**
Peritonitis, indicated by cloudy effluent, later abdominal pain, fever, and general malaise or, in very rare cases, sepsis; 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, encapsulating peritoneal sclerosis; dyspnoea caused by the elevated diaphragm; hernia; abdominal distension and sensation of fullness; shoulder pain.

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

**Date:** December 2019

**Fresenius Medical Care Deutschland GmbH**
Else-Kröner-Straße 1, 61352 Bad Homburg v.d.H., Germany