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.
Prescription only medicine.

Date: January 2020

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

Abbreviated Prescribing Information

bica*Vera* 1.5 % Glucose, 1.75 mmol/l Calcium, Solution for peritoneal dialysis
bica*Vera* 2.3 % Glucose, 1.75 mmol/l Calcium, Solution for peritoneal dialysis
bica*Vera* 4.25 % Glucose, 1.75 mmol/l Calcium, Solution for peritoneal dialysis
bica*Vera* 1.5 % Glucose, 1.25 mmol/l Calcium, Solution for peritoneal dialysis
bica*Vera* 2.3 % Glucose, 1.25 mmol/l Calcium, Solution for peritoneal dialysis
bica*Vera* 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:

bica*Vera* 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)

bica*Vera* 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)

bica*Vera* 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)

bica*Vera* 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)

bica*Vera* 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)

bica*Vera* 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 bicaVera or not all strengths of bicaVera are registered or marketed in your country.
Prescription only medicine.

Date: December 2019

Fresenius Medical Care Deutschland GmbH
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