

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

Abbreviated Prescribing Information

bicaNova 1.5 % Glucose, Solution for peritoneal dialysis

bicaNova 2.3 % Glucose, Solution for peritoneal dialysis

bicaNova 4.25 % Glucose, 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:

bicaNova 1.5 % Glucose: calcium chloride dihydrate 0.1838 g, sodium chloride 5.495 g, sodium hydrogen carbonate 3.360 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 16.5 g (glucose 15.0 g)

bicaNova 2.3 % Glucose: calcium chloride dihydrate 0.1838 g, sodium chloride 5.495 g, sodium hydrogen carbonate 3.360 g, magnesium chloride hexahydrate 0.1017 g, glucose monohydrate 25.0 g (glucose 22.73 g)

bicaNova 4.25 % Glucose: calcium chloride dihydrate 0.1838 g, sodium chloride 5.495 g, sodium hydrogen carbonate 3.360 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 related:

bicaNova 1.5 % Glucose: severe hypokalaemia, severe hypocalcaemia

bicaNova 2.3 % Glucose, bicaNova 4.25 % Glucose: severe hypokalaemia, severe hypocalcaemia, hypovolaemia, 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); localized 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 the 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, hypocalcaemia; 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 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 *bicaNova* or not all strengths of *bicaNova* 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

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 related:

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, 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); localized 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 bicaVera or not all strengths of bicaVera 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

Abbreviated Prescribing Information

CAPD/DPCA 2, solution for peritoneal dialysis

CAPD/DPCA 3, solution for peritoneal dialysis

CAPD/DPCA 4, solution for peritoneal dialysis

CAPD/DPCA 17, solution for peritoneal dialysis

CAPD/DPCA 18, solution for peritoneal dialysis

CAPD/DPCA 19, solution for peritoneal dialysis

Composition:

1 litre solution contains:

CAPD/DPCA 2: calcium chloride dihydrate 0.2573 g, sodium chloride 5.786 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)

CAPD/DPCA 3:

calcium chloride dihydrate 0.2573 g, sodium chloride 5.786 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)

CAPD/DPCA 4:

calcium chloride dihydrate 0.2573 g, sodium chloride 5.786 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)

CAPD/DPCA 17:

calcium chloride dihydrate 0.1838 g, sodium chloride 5.786 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)

CAPD/DPCA 18:

calcium chloride dihydrate 0.1838 g, sodium chloride 5.786 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)

CAPD/DPCA 19:

calcium chloride dihydrate 0.1838 g, sodium chloride 5.786 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)

Excipients:

Water for injections, hydrochloric acid, sodium hydroxide.

Indications:

End-stage chronic renal failure requiring treatment with peritoneal dialysis.

Contraindications:

Solution related:

Solutions containing 1.75 mmol/l calcium: severe hypokalaemia, severe hypercalcaemia.

Solutions containing 1.25 mmol/l calcium: severe hypokalaemia, severe hypocalcaemia.

Solutions containing 2.3% or 4.25% glucose additionally: hypovolaemia, arterial hypotension.

Metabolism disorders (hereditary fructose intolerance, lactic acidosis).

Treatment related:

Recent abdominal surgery or injury; a history of abdominal operations with fibrous adhesions; abdominal burns; perforation of the bowel (gut); inflammation of the skin of the abdomen, for example dermatitis; inflammation of the

bowel, for example Crohn's disease, ulcerative colitis, diverticulitis; peritonitis (inflammation in the abdomen); abdominal fistulae (non-healing weeping wounds); hernias; tumours in the abdomen or bowel; obstruction in the bowel (ileus); lung disease (particularly pneumonia); blood poisoning (sepsis); extreme weight loss (cachexia) and particularly when adequate protein intake is not possible; uraemia (the accumulation of toxins in the blood caused by kidney failure) where it is known that peritoneal dialysis is not useful and is not an appropriate treatment; very high levels of fat in the blood (hyperlipidaemia).

Side effects:

Treatment related:

Frequently peritonitis - inflammation of the peritoneum characterised by the presence of a cloudy dialysate (solution) seen during drain out, abdominal pain, general malaise/generally feeling unwell, fever and, if untreated, generalised blood poisoning - and inflammation around the catheter which can be recognised by redness, swelling, weeping, crusts and pain at the catheter exit site.

In addition the peritoneal dialysis treatment can cause abdominal swelling and a feeling of fullness, hernia, shoulder pain, shortness of breath due to the diaphragm being pushed upwards, diarrhoea and constipation. Disturbance or restriction of the in flow and out flow of dialysis solution into and out of the peritoneal cavity may also occur.

Solution related:

Fluid and electrolyte imbalance, which might include decreased calcium levels (for solutions containing 1.25 mmol/l calcium), decreased potassium levels, or increased calcium levels in combination with an increased calcium intake, e.g. through administration of calcium-containing phosphate binders (for solutions containing 1.75 mmol/l calcium), an overactive parathyroid gland leading to possible bone disorders (for solutions containing 1.25 mmol/l calcium), symptoms of fluid build up (e.g. swelling, shortness of breath), dehydration (e.g. dizziness, muscle cramps), increased blood sugar levels, increased weight due to the continuous glucose (sugar) uptake and disorders of lipid (fat) metabolism. Increased heart beat (tachycardia), low blood pressure and high blood pressure have been reported.

Warnings and precautions:

Contains fructose.

Possibly CAPD/DPCA 2,3,4,17,18,19 or not all strengths of CAPD/DPCA 2,3,4,17,18,19 are registered or marketed in your country.

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