Abbreviated Prescribing Information

bica*Vera* 1.5 % Glucose, Solution for peritoneal dialysis
bica*Vera* 2.3 % Glucose, Solution for peritoneal dialysis
bica*Vera* 4.25 % Glucose, Solution for peritoneal dialysis

bicaVera 1.5 % / 2.3 % / 4.25 % Glucose is 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: sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, anhydrous glucose (as glucose monohydrate) 15 g.

bica*Vera* 2.3 % Glucose: sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, anhydrous glucose (as glucose monohydrate) 22.73 g.

bica*Vera* 4.25% Glucose: sodium chloride 5.786 g, sodium hydrogen carbonate 2.940 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, anhydrous glucose (as glucose monohydrate) 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:
bica*Vera* 1.5% Glucose: severe hypokalaemia, severe hypercalcaemia
bica*Vera* 2.3% Glucose, bicaVera 4.25% Glucose: severe hypokalaemia, severe hypercalcaemia, hypovolaemia, hypotension.

For peritoneal dialysis in general:
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; in rare cases of uraemia, which can not be managed by peritoneal dialysis; cachexia and severe weight loss, particularly in cases in which the ingestion of adequate protein is not guaranteed; patients who are physically or mentally incapable of performing PD as instructed by the physician.

Side effects

Solution specific:

Electrolyte disturbances, e.g. hypokalaemia, hypercalcaemia in combination with an increased calcium uptake, e.g. by the administration of calcium-containing phosphate binders; disturbances in hydration. A rapid decrease in body weight, the drop in blood pressure and/or tachycardia may indicate dehydration;

oedema, hypertension and possibly dyspnoea may indicate overhydration; increased blood sugar levels; hyperlipidaemia; increase in body weight.

For peritoneal dialysis in general:

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

Warnings and Precautions

Do not use unless the solution is clear and the container is undamaged. For single use only. Any unused residual solution should be discarded. Do not use before the two solutions have been mixed. The ready-to-use solution must be used within 24 hours after mixing. Do not store below 4°C.

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