PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The dispensing of this medicine requires a doctor's prescription

Read this package insert carefully in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in November 2010

bicaVera bicaVera bicaVera

1.5% Glucose, 1.75 mmol/l Calcium Solution for peritoneal dialysis

2.3% Glucose, 1.75 mmol/l Calcium Solution for peritoneal dialysis

4.25% Glucose, 1.75 mmol/l Calcium Solution for peritoneal dialysis

Composition per liter:

bicaVera 1.5% Glucose, 1.75 mmol/l Calcium:
Sodium Chloride 5.786 g, Sodium Hydrogen Carbonate 2.940 g, Calcium Chloride dihydrate 0.2573 g, Glucose Anhydrous 15 g, Magnesium Chloride Hexahydrate 0.1017 g

bicaVera 2.3% Glucose, 1.75 mmol/l Calcium:
Sodium Chloride 5.786 g, Sodium Hydrogen Carbonate 2.940 g, Calcium Chloride dihydrate 0.2573 g, Glucose Anhydrous 22.73 g, Magnesium Chloride Hexahydrate 0.1017 g

bicaVera 4.25% Glucose, 1.75 mmol/l Calcium:
Sodium Chloride 5.786 g, Sodium Hydrogen Carbonate 2.940 g, Calcium Chloride dihydrate 0.2573 g, Glucose Anhydrous 42.5 g, Magnesium Chloride Hexahydrate 0.1017 g

Therapeutic group: Electrolytes solutions

Therapeutic activity:

bicaVera solutions are intended for the treatment of patients who suffer from chronic renal failure and are being treated with peritoneal dialysis.

When should the preparation not be used?

Do not use this medicine if you are suffering from potassium deficiency, high blood calcium levels, low blood pressure or low plasma volume.
If you are suffering from intra-abdominal perforation, from an intra-abdominal tumor, from a hernia, from abdominal fistula, from intestinal obstruction, from abdominal injury, from severe abdominal burns, if you have recently had abdominal surgery.
If you are suffering from a lung disease (especially pneumonia), from severe hyperlipidaemia.
If you are suffering from fibrinous adhesions as a result of previous surgery or due to any other reason.
If you are suffering from inflammatory bowel disease, from fatigue and severe weight loss (cachexia), from peritonitis, from extensive inflammatory abdominal skin reaction, from sepsis.

Do not take this medicine without consulting a doctor before starting treatment:

If you are pregnant or breastfeeding. In case of vomiting or diarrhoea.

Warnings:

Creatinine and urea levels should be checked regularly.
During treatment with this medicine, blood levels of sodium, potassium, calcium, glucose, magnesium, phosphate, acid base status and proteins should be monitored, as well as the patient's weight and residual renal function.
If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Drug interactions:

If you are taking another drug concomitantly, including non-prescription medicines and food supplements, or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.
Other medications may only be added after they have been proved compatible with the dialysis solution.
In diabetic patients the daily dose of medicines for blood sugar reduction must be adjusted to the increased glucose load.
Potassium blood levels should be carefully monitored in patients taking digoxin.

Side effects:

In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example:

Effects related to the catheter:
Abdominal pain, bleeding, peritonitis, subcutaneous inflammation around the catheter, blocked catheter, difficulty in fluid removal, intestinal obstruction or diarrhea, shoulder pain.

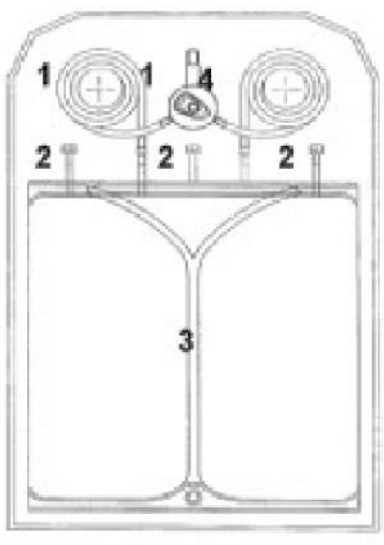
Effects related to the solution:
Fluid and electrolyte imbalance, e.g. increase or decrease in potassium and calcium levels, dehydration that may be indicated in rapid decrease in body weight, a drop in blood pressure and/or tachycardia, lack of equilibrium, muscle pain, overhydration that may be indicated in oedema, hypertension and shortness of breath, high or low plasma volume, loss of protein, increase in body weight, increased blood sugar levels, hyperlipidemia.
In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Dosage: According to doctor's instructions only.
The treatment is performed daily in accordance with the indicated dosage.

Directions for use:

Solution for peritoneal dialysis only.
Check the expiry date and make sure the solution is clear and colorless and the bag is not damaged.
Ensure that aseptic conditions are maintained and wash your hands with an antimicrobial soap, according to the medical crew instructions.
The solutions must be mixed before use. The instillation time for each dose is 5-20 minutes.
According to the doctor's instructions, the indwelling time is 2-10 hours after which it must be drained.

Stay-safe system (see diagram)



1. Tubing
2. Injection/sample port or plug
3. Peel seam
4. DISC system connector

Warming the solution bag:
1. Warm the solution bag to body temperature by using an appropriate heater tray **(DO NOT** use the microwave to warm the solution bag).

Mixing the solutions:
2. Disinfect a straight, stable work surface and place the bag on it.
3. Remove the outer wrapping and the package of the disinfection cap.
4. Wash your hands with an antimicrobial soap.
5. Roll up the bag from one of the upper ends until the middle seam opens (3). The solutions in the two chambers are mixed automatically.
6. Then roll up the bag from the upper edge, until the peel seam of the lower triangle is completely opened.
7. The ready-to-use solution should be used within 24 hours after mixing.

Preparation of the bag exchange:
8. Hang the solution bag on the upper hook of the infusion pole.
9. Unroll the tubing line of the solution bag.
10. Place the DISC into the organizer.
11. Unroll the tubing line of the drainage bag and hang the drainage bag on the lower hook of the infusion pole.
12. Place catheter adapter into the organizer.
13. Disinfect your hands and remove the protection cap of the DISC.
14. Connect catheter adapter to the DISC.

Outflow
15. Open the catheter clamp. The "●" position indicates that the outflow process has begun.

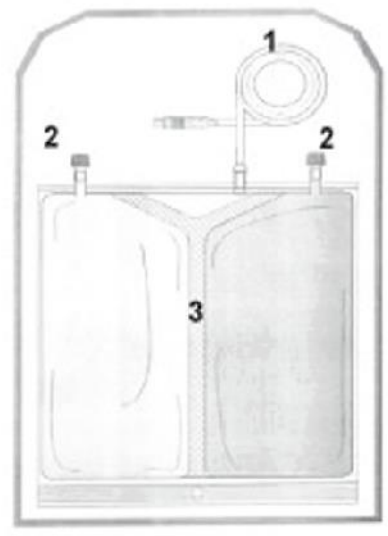
Flush
16. The "●●" position indicates that the flush of fresh dialysate to the drainage bag (approx. 5 seconds) is occurring.

Inflow
17. Inflow position "○◑●" indicates that there is a connection between the solution bag and the catheter.

Security stop
18. Security stop position "●●●●" indicates automatic closing of the catheter adapter with the PIN.

Disconnection
19. Remove the catheter adapter from the DISC and screw the new disinfection cap to the catheter adapter.
20. Close the DISC with the open end of the protection cap of the used disinfection cap (which is placed in the right hole of the organizer).
21. Check the drained dialysate and dispose of it.

Sleep-safe system (see diagram)



1. Tubing
2. Injection port or plug
3. Peel seam

Mixing the solutions:
1. Disinfect a straight, stable work surface and place the bag on it.
2. Remove the outer wrapping and the package of the disinfection cap.
3. Wash your hands with an antimicrobial soap.
4. Roll up the bag from one of the upper ends until the middle seam opens (3). The solutions in the two chambers are mixed automatically.
5. Then roll up the bag from the upper edge, until the peel seam of the lower triangle is completely opened.
6. The ready-to-use solution should be used within 24 hours after mixing.
7. Unroll tubing of bag (1).
8. Remove the protection cap.
9. Insert connector into the free sleep-safe tray port.
10. The bag is now ready for use with the sleep-safe set.

Presentation:

4 bags of 1,500 ml each
4 bags of 2,000 ml each
4 bags of 2,500 ml each
4 bags of 3,000 ml each
2 bags of 5,000 ml each

Avoid poisoning!

This medicine, and all other medicines, must be stored in a safe place out of the reach children and/or infants, to avoid poisoning.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of medicine with you.
Do not induce vomiting unless explicitly instructed to do so by a doctor!
This medicine has been prescribed for the treatment of your ailment, in another patient it may cause harm. **Do not give this medicine to your relatives, neighbours or acquaintances.**
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if your need them.

Storage: Do not store below 4°C.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package.

Licence number:

bicaVera 1.5% Glucose, 1.75 mmol/l Calcium: 1325331018
bicaVera 2.3% Glucose, 1.75 mmol/l Calcium: 1325131019
bicaVera 4.25% Glucose, 1.75 mmol/l Calcium:1325231020

Manufacturer: Fresenius Medical Care, Germany

Registration holder: NEPHROMED LTD. 7 Carlebach Street, Tel Aviv, Israel