bica*Vera*
1.5 % Glucose,
1.75 mmol/l Calcium

Package leaflet:
Information for the user
bica*Vera* 1.5 % Glucose, 1.75 mmol/l Calcium,
Solution for peritoneal dialysis

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What is in this leaflet

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

1. What bica*Vera* is and what it is used for

bica*Vera* is used for cleaning the blood via the peritoneum in patients with end-stage chronic kidney failure. This type of blood cleaning is called peritoneal dialysis.

2. What you need to know before you use bica*Vera*

Do not use bica*Vera* 1.5 % Glucose, 1.75 mmol/l Calcium
- if the level of **potassium in your blood is very low**
- if the level of **calcium in your blood is very high**

Peritoneal dialysis treatment must not be started if you have
- alterations in the abdominal region such as
  – injuries, or after surgery
  – severe burns
  – large, inflammatory skin reactions
  – inflammation of the peritoneum
  – non-healing, weeping wounds
  – umbilical, inguinal or diaphragmatic hernias
  – tumours in the abdomen or bowel
- inflammatory bowel diseases
- intestinal obstruction
- lung diseases, particularly pneumonia
- blood poisoning caused by bacteria
- extremely high levels of fat in the blood
- poisoning due to urine products in the blood which cannot be treated by peritoneal dialysis
- severe malnutrition and loss of weight, particularly if adequate intake of food containing proteins is not possible.

Warnings and precautions
Inform your doctor immediately
- if you have **a severe loss of electrolytes (salts)** due to vomiting and/or diarrhoea.
- if you have **an inflammation of the peritoneum,** recognisable by a cloudy dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning. Please show the bag containing the drained dialysate to your doctor.
- if you have **severe abdominal pain, abdominal distension or vomiting.** This can be a sign of encapsulating peritoneal sclerosis, a complication of the peritoneal dialysis therapy that can be fatal.

Peritoneal dialysis can lead to a **loss of proteins** and **water-soluble vitamins.** An adequate diet or nutritional supplements are recommended in order to avoid deficiency states.

Your doctor will check your electrolyte (salt) balance, blood cell counts, kidney function, body weight and nutritional state.

Other medicines and bica*Vera*
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Because peritoneal dialysis may influence the effects of medicines, your doctor may need to change their dosages, especially those of
- **Medicines for heart failure,** such as digitoxin. Your doctor will check the level of potassium in your blood and, if necessary, will take appropriate measures.
- **Medicines that influence calcium levels** such as those containing calcium or vitamin D.
- **Medicines that increase the excretion of urine** such as diuretics.
- **Medicines** taken by mouth **that lower blood sugar levels** or insulin. Your blood sugar level should be measured regularly.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

There are no adequate data from the use of bica*Vera* in pregnant women or during lactation period. If you are pregnant or breast-feeding you should use bica*Vera* only if your doctor considers this absolutely necessary.

Driving and using machines
bica*Vera* has no or negligible influence on the ability to drive and use machines.

3. How to use bica*Vera*

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will determine the method, duration and frequency of use and the required volume of solution and dwell time in the peritoneal cavity.

If tension in the abdominal region occurs your doctor may reduce the volume.

Continuous ambulatory peritoneal dialysis (CAPD)
- **Adults:** the usual dose is 2000 - 2500 ml solution four times daily depending on body weight and kidney function.
  After 2-10 hours dwell time the solution is drained off.
- **Children:** The doctor will determine the volume of dialysis solution required depending on the tolerance, age and body surface area of the child.
  The recommended initial dose is 600-800 ml/m^2 (up to 1000 ml/m^2 overnight) body surface area four times daily.

Automatic peritoneal dialysis (APD)
For this the bica*Vera sleep•safe* system is used. Bag exchange is controlled automatically by the *sleep•safe* cycler overnight.
- **Adults:** The usual prescription is 2000 ml (maximum 3000 ml) per exchange with 3-10 exchanges overnight and time on the cycler 8 to 10 hours, and at daytime one or two exchanges.
- **Children:** The volume per exchange should be 800-1000 ml/m^2 (up to 1400 ml/m^2) body surface area with 5-10 exchanges overnight.

Use bica*Vera* in the **peritoneal cavity only.**

Use bica*Vera* only if the solution is clear and the bag is undamaged.

bica*Vera* is available in a double-chamber bag. Before use the solutions in the two chambers must be mixed as described.

Handling instructions
***stay•safe*® system for continuous ambulatory peritoneal dialysis (CAPD)**

The solution bag is first warmed to body temperature. This should be done by using an appropriate heater tray. The heating time for a 2000 ml bag with a starting temperature of 22°C is approximately 120 min.

More detailed information can be obtained from the operating instructions of the bag warmer. A microwave oven must not be used to warm the solution due to the risk of local overheating. After warming the solution you can start with the exchange of the bags.

1. Preparation of the solution

▸ Place the bag on a solid surface. ▸ Open the overwrap of the bag and seal of the disinfection cap. ▸ Check the solution bag before use (label, expiry date, clearness of the solution, integrity of the bag). ▸ Wash your hands with an antimicrobial washing lotion. ▸ Roll up the bag from one of the upper ends until the middle seam opens. The solutions in the two chambers are mixed automatically. ▸ Then roll up the bag from the upper edge, until the peel seam of the lower triangle is completely opened. ▸ The ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing!

2. Preparation of the bag exchange

▸ Hang the solution bag on the upper hook of the infusion pole, unroll the tubing line of the solution bag, and place the DISC into the organizer. After unrolling the tubing line to the drainage bag, hang the drainage bag on the lower hook of the infusion pole and place the disinfection cap into the organizer. ▸ Place catheter adapter into the organizer. ▸ Disinfect your hands and remove the protection cap of the DISC. ▸ Connect catheter adapter to the DISC.

3. Outflow

▸ Open the catheter clamp. The outflow starts.
▸ Position ●

4. Flush

▸ Flush the drainage bag with fresh solution (approximately 5 seconds). ▸ Position ●●

5. Inflow

▸ Connect the solution bag with the catheter.
▸ Position ○◑●

6. Security step

▸ Close the catheter adapter by putting in the PIN.
▸ Position ●●●●

7. Disconnection

▸ Remove the catheter adapter from the DISC and screw the new disinfection cap to the catheter adapter.

8. Closure of the DISC

▸ 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.

9. Check the drained dialysate and dispose of it.

***sleep•safe* system** for **automatic peritoneal dialysis (APD)**

During automatic peritoneal dialysis (APD) the solution is warmed automatically in the machine.

1. Preparation of the solution

▸ Check the solution bag (label, expiry date, clearness of the solution, bag and overwrap are not damaged, peel seams are intact). ▸ Place the bag on a solid surface. ▸ Open the overwrap of the bag. ▸ Wash your hands with an antimicrobial washing lotion. ▸ Unfold middle seam and bag connector. ▸ Roll up the bag, which is lying on the overwrap, from the diagonal end towards the bag connector. The middle peel seam will open. ▸ Continue until the peel seam of the small chamber opens as well. ▸ Check that all peel seams are completely open. ▸ Check that the solution is clear and that the bag is not leaking.

2. Unroll tubing of bag.

3. Remove the protection cap and insert the bag connector in one of the free tray ports of the *sleep•safe* cycler.

4. The bag is now ready for use with the *sleep•safe* set.

Each bag should be used only once and any unused solution remaining must be discarded.

After appropriate training, bica*Vera* can be used independently at home. Ensure that you follow all the procedures you learnt during training and maintain hygienic conditions when exchanging bags.

Always check the drained dialysate for cloudiness. See section 2. "Warnings and precautions".

If you use more bica*Vera* than you should
If you allow too much solution to flow into the peritoneal cavity, the excess can be drained off. If you use too many bags please contact your doctor as this can result in fluid and/or electrolyte imbalances.

If you forget to use bica*Vera*
Try to attain the volume of dialysate prescribed for each 24-hour period in order to avoid the risk of possibly life-threatening consequences. You should check with your doctor if you are not sure.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, bica*Vera* can cause side effects, although not everybody gets them.

The following side effects may occur as a result of the peritoneal dialysis treatment in general:

very common (may affect more than 1 in 10 people):
- inflammation of the peritoneum with signs of cloudiness of the drained dialysate, abdominal pain, fever, feeling unwell or in very rare cases blood poisoning. Please show the bag containing the drained dialysate to your doctor.
- inflammation of the skin at the catheter exit site or along the length of the catheter, recognisable by redness, swelling, pain, weeping or crusts.
- hernia of the abdominal wall.

Please contact your doctor immediately if you notice any of these side effects.

Other side effects of the treatment are:

common (may affect up to 1 in 10 people):
- problems with inflow or outflow of the dialysate
- sensation of stretching or fullness of the abdomen
- shoulder pain

uncommon (may affect up to 1 in 100 people):
- diarrhoea
- constipation

not known (frequency cannot be estimated from available data):
- breathing difficulties due to elevation of the diaphragm.
- encapsulating peritoneal sclerosis, possible symptoms may be abdominal pain, abdominal distension or vomiting.

The following side effect may occur when bica*Vera* is used:

very common (may affect more than 1 in 10 people):
- potassium deficiency

common (may affect up to 1 in 10 people):
- high blood sugar levels
- high blood fat levels
- weight gain

uncommon (may affect up to 1 in 100 people):
- calcium excess if the calcium intake is too high
- body fluid levels too low, which can be recognised by rapid weight loss
- low blood pressure
- rapid pulse
- body fluid levels too high, which can be recognised by rapid weight gain
- water in the tissues and lung
- high blood pressure
- breathing difficulties

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store bica*Vera*

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bag and carton after "EXP". The expiry date refers to the last day of that month.

Do not store bica*Vera* below 4 °C.

The ready-to-use solution should be used immediately, but within a maximum of 24 hours after mixing.

Do not use this medicine if you notice that the solution is not clear or the bag is damaged.

6. Contents of the pack and other information

What bica*Vera* contains
The active substances in one litre of the ready-to-use solution are:

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 (equivalent to 15.0 g glucose)	16.5 g

These quantities of active substances are equivalent to: 1.75 mmol/l calcium, 134 mmol/l sodium, 0.5 mmol/l magnesium, 104.5 mmol/l chloride, 34 mmol/l hydrogen carbonate and 83.25 mmol/l glucose.

The other ingredients of bica*Vera* are water for injections, hydrochloric acid, sodium hydroxide, carbon dioxide.

What bica*Vera* looks like and contents of the pack

The solution is clear and colourless.

The theoretical osmolarity of the ready-to-use solution is 358 mOsm/l, the pH is about 7.40.

bica*Vera* is a solution for peritoneal dialysis and available in a double-chamber bag. One chamber contains the alkaline sodium hydrogen carbonate solution and the other the acidic glucose-based electrolyte solution in a ratio of 1:1.

bica*Vera* is available in the following application systems and pack sizes per carton:

stay•safe®	*sleep•safe*
4 × 2000 ml bags	4 × 2000 ml bags
4 × 2500 ml bags	4 × 2500 ml bags
4 × 3000 ml bags	4 × 3000 ml bags
	2 × 5000 ml bags

Not all pack sizes may be marketed.

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

Manufacturer
Fresenius Medical Care Deutschland GmbH,
Frankfurter Straße 6–8, 66606 St. Wendel, Germany

Local Representative
Fresenius Medical Care (UK) Ltd,
Tel.: 0044 (0) 1623 445 100

This medicinal product is authorised in the Member States of the EEA under the following names:
See end of this multilingual package leaflet.

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POM