

bicaVera

4.25 % Glucose,

1.25 mmol/l Calcium

Package leaflet:

Information for the user

bicaVera 4.25 % Glucose, 1.25 mmol/l Calcium, Solution for peritoneal dialysis

What is in this leaflet

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2. What you need to know before you use bicaVera
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1. What bicaVera is and what it is used for

bicaVera 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 bicaVera

Do not use bicaVera 4.25 % Glucose, 1.25 mmol/l Calcium

- if the level of **potassium in your blood is very low**
- if the level of **calcium in your blood is very low**
- if the **volume of your body fluids is too low**
- if you have **low blood pressure**

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 **overactive parathyroid** or a **low calcium level in your blood**, it may be necessary to take additional calcium-containing phosphate binders and/or vitamin D. If this is not possible a peritoneal dialysis solution with a higher calcium concentration may be necessary.
- 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 **polycystic kidneys**.
- 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.

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.

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

Other medicines and bicaVera

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 bicaVera in pregnant women or during lactation period. If you are pregnant or breast-feeding you should use bicaVera only if your doctor considers this absolutely necessary.

Driving and using machines

bicaVera has no or negligible influence on the ability to drive and use machines.

3. How to use bicaVera

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/m² (up to 1000 ml/m² overnight) body surface area four times daily.

Automatic peritoneal dialysis (APD)

For this the bicaVera *sleep•safe* system is used. Bag exchange is controlled automatically by the *sleep•safe* cyclers overnight.

- **Adults:** The usual prescription is 2000 ml (maximum 3000 ml) per exchange with 3-10 exchanges overnight and time on the cyclers 8 to 10 hours, and at daytime one or two exchanges.
- **Children:** The volume per exchange should be 800-1000 ml/m² (up to 1400 ml/m²) body surface area with 5-10 exchanges overnight.

Use bicaVera in the **peritoneal cavity only**.

Use bicaVera only if the solution is clear and the bag is undamaged.

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

Handling instructions

For use of the *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 bag warmer. 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

◆ Check the warmed solution bag (label, expiry date, clearness of the solution, bag and overwrap not damaged, peel seams intact). ◆ Place the bag on a solid surface. ◆ Open the overwrap of the bag and the packaging of the disinfection cap. ◆ Wash your hands with an antimicrobial washing lotion. ◆ Roll up the bag, which is lying on the overwrap, from one of the side edges until the middle seam opens. The solutions in the two chambers are mixed automatically. ◆ Now roll up the bag from the upper edge until the peel seam of the lower triangle is completely open. ◆ Check that all peel seams are completely open. ◆ Check that the solution is clear and that the bag is not leaking.

2. Preparation of the bag exchange

◆ Hang the solution bag in the upper hole 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 in the lower hole of the infusion pole. ◆ Place catheter connector into one of the two inserts of the organizer. ◆ Place the new disinfection cap into the other free insert. ◆ Disinfect your hands and remove the protection cap of the DISC. ◆ Connect catheter connector to the DISC.

3. Outflow

- ▶ Open the clamp on the extension. The outflow starts.
- ▶ Position ●

4. Flush

- ▶ After completion of outflow flush fresh solution into the drainage bag (approx. 5 seconds). ▶ Position ●●

5. Inflow

- ▶ Start inflow by turning the control switch to
- ▶ Position ○●●

6. Safety step

- ▶ Close the catheter extension by introducing the PIN into the catheter connector.
- ▶ Position ●●●●
- ▶ Close the clamp on catheter extension.

7. Disconnection

- ▶ Remove protection cap from the new disinfection cap and screw it onto the old one. ▶ Screw the catheter connector off the DISC and screw the catheter connector to the new disinfection cap.

8. Closure of the DISC

- ▶ Close the DISC with the open end of the used disinfection cap, which has remained in the right hole of the organizer.

9. Check the drained dialysate for clarity and weight and if the effluent is clear discard it.

For use of the *sleep•safe* system for automatic peritoneal dialysis (APD)

During automated peritoneal dialysis (APD) the solution is warmed automatically by the cyclor.

3000 ml *sleep•safe* system

1. Preparation of the solution: see *stay•safe*® system
2. Unroll tubing of bag.
3. Remove the protection cap.
4. Insert bag connector in free tray port of the *sleep•safe* cyclor.
5. The bag is now ready for use with the *sleep•safe* set.

5000 ml *sleep•safe* system

1. Preparation of the solution

- ▶ Check the solution bag (label, expiry date, clearness of the solution, bag, and overwrap not damaged, peel seams intact). ▶ Place the bag on a solid surface.
 - ▶ Open the overwrap of the bag. ▶ Wash your hands with an antimicrobial washing lotion. ▶ Unfold middle peel 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.
- 2-5.: see 3000 ml *sleep•safe* system

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

After appropriate training, *bicaVera* 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 *bicaVera* 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 *bicaVera*

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, *bicaVera* 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 *bicaVera* 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 deficiency
- 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

not known (frequency cannot be estimated from available data):

- overactive parathyroid with potential disturbances of bone metabolism

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 *bicaVera*

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.

bicaVera stay•safe® / *sleep•safe*:
 Do not store below 4 °C.
bicaVera sleep•safe combo:
 Store at 5 °C - 30 °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 *bicaVera* contains

The active substances in one litre of the ready-to-use solution are:

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 (equivalent to 42.5 g glucose)	46.75 g

These quantities of active substances are equivalent to: 1.25 mmol/l calcium, 134 mmol/l sodium, 0.5 mmol/l magnesium, 103.5 mmol/l chloride, 34 mmol/l hydrogen carbonate and 235.9 mmol/l glucose. The other ingredients of *bicaVera* are water for injections, hydrochloric acid, sodium hydroxide, carbon dioxide.

What *bicaVera* looks like and contents of the pack

The solution is clear and colourless.

The theoretical osmolarity of the ready-to-use solution is 509 mOsm/l, the pH is about 7.4.

bicaVera is 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.

bicaVera is a solution for peritoneal dialysis and available in the following application systems and pack sizes per carton:

<i>stay•safe</i> ®	<i>sleep•safe</i>
4 × 2000 ml bags	4 × 3000 ml bags
4 × 2500 ml bags	2 × 5000 ml bags
<i>sleep•safe combo</i>	
2 x 5000 ml bags + disinfection cap + <i>sleep•safe</i> Set Plus	

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

bicaVera stay•safe® / *sleep•safe*:
 Fresenius Medical Care Deutschland GmbH,
 Frankfurter Straße 6–8, 66606 St. Wendel, Germany
bicaVera sleep•safe combo:
 Fresenius Medical Care Deutschland GmbH,
 Else-Kröner-Straße 1,
 61352 Bad Homburg v.d.H., 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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