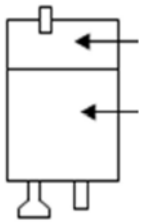
Sterile solution for haemofiltration/ haemodiafiltration/ haemodialysis PRISMASOL B0

1. What is this medicine?

1.1 What is in the medicine?

1) This medicine is a solution for haemofiltration, haemodiafiltration and continuous haemodialysis which is a combination of **5 active ingredients**, the generic name as following
1) Calcium chloride dihydrate
2) Magnesium chloride hexahydrate and
3) Lactic acid.
This is the electrolyte solution (in the small compartment A) with
4) Sodium bicarbonate and
5) Sodium chloride
This is the buffer solution (in the large compartment B).



Small compartment A

Large compartment B

1.2 What is this medicine used for?

- Treatment of acute kidney disease (renal failure) as substitution solution in continuous haemofiltration and continuous haemodiafiltration and as a dialysis solution in continuous haemodialysis and continuous haemodiafiltration.

2. Before you are given this medicine

2.1 When should you not take this medicine?

- Allergic to one of the active substances or any of the other ingredients

2.2 Warning and Precautions

- Caution when using this medicine **in pregnancy and breastfeeding** Tell your doctor if you are pregnant or breastfeeding since **there are no adequate data on the use of this medicine**.

- Tell your doctor if you are taking any other medicines since taking this medicine with some medicines may affect the treatment outcome or be dangerous.
- **Before and during treatment, the level of potassium, concentrations of salts (electrolytes) and acid-base balance in the blood should be monitored** since **this medicine is potassium-free**

3. Dosage and Administration

3.1 How much and how often should you use this medicine?

- Use **in the hospitals or nursing houses**
- **This medicine should be used only by, or under the direction of a physician competent in renal failure treatments** using haemofiltration, haemodiafiltration and continuous haemodialysis since the dosage and duration depend on the disease severity. And this medicine needs to be used with a device for Continuous Renal Replacement Therapy. Fluid balance and blood chemistry should be monitored.
- Before use, check the solution and use only if the solution is clear, colorless and the overwrap is undamaged. All seals must be intact. Discard the solution if the solution is not clear or leakage is discovered.
- The two compartments (small compartment A and large compartment B) must be mixed before use.
- Mix additives before connecting the bag to the extracorporeal circuit.
- **The reconstituted solution must be used within 24 hours but it should be used immediately after the primary packaging is opened**.

3.2 What to do when you have taken more than the recommended dosage?

- Observe the signs and symptoms closely. If any of the side effects get serious such as congestive heart failure (dyspnea, fatigue, shortness of breath, orthopnea, swelling of feet or leg) or disturbances in your blood chemistry (result from laboratory chemistry), **please inform your doctor immediately.**

4. Care that should be taken when taking this medicine

- Do not discontinue the medicine on your own. Use this medicine as directed by physician
- During treatment, **the level of potassium, concentrations of salts (electrolytes) and acid-base balance in the blood should be monitored.** Phosphate substitution and potassium supplement might be necessary.

5. Side effects

5.1 Should you have the following symptom

- Swelling of face, eyelid, lip. Urticaria
- Faint, chest discomfort, shortness of breath
- Erythema, blistering, skin detachment, skin bruise or abnormal bleeding

discontinue the medicine and immediately contact your doctor

5.2 Should you have the following symptom

- Low blood pressure (hypotension)
- Electrolyte disturbances, especially low level of potassium in the blood.
- Low levels of phosphate in the blood (Hypophosphatemia)
- Elevation (metabolic alkalosis) or reduction (metabolic acidosis) of the plasma bicarbonate concentration by finding following symptoms: muscular spasms, muscle cramps, muscle weakness, muscle pain, beriberi, lassitude, easy fatigability, confusion, headache, seizures
- Abnormally high or low volume of water in the body (hypo or hypervolemia) by finding following symptoms: dizziness, thirst, low urine volume, increase in weight, swelling in the legs, arms and face
- Nausea, vomiting
- Arrhythmia

it is not necessary to discontinue the medicine but immediately contact the physician if the side effects get more severe

6. How should you keep this medicine?

- Store in the original package.
- Store in dry place. Avoid storage in direct sunlight. Store below 30°C. Do not store in humid or heat.
- Do not refrigerate. Do not freeze
- Do not use after the expiry date shown on the label and the packaging.
- The reconstituted solution **must be used within 24 hours.** Once opened, the product should be used immediately.

7. Description and composition

- Two-compartment bag containing a clear and colorless solution
- Active ingredients i.e. Calcium chloride dihydrate, Magnesium chloride hexahydrate, Lactic acid, Sodium bicarbonate and Sodium chloride
- Excipients i.e. Carbon dioxide and Water for injections

Manufacturer BIEFFE MEDITAL S.P.A. VIA STELVIO, 94-23035 SONDALO (SO), Italy
Importer and distributor Baxter Healthcare (Thailand) Co.,Ltd. Bangkok, Thailand

Date of revision of PIL
11 July 2019

This is a brief information. If you have any questions, please ask your doctor or pharmacist