Prismasol B0

Baxter

IN | Package leaflet

Solution for haemofiltration and haemodialysis.
Read all of this leaflet carefully before you start using this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

PRISMASOL B0
Solution for haemofiltration and haemodialysis.

WHAT DOES PRISMASOL B0 CONTAIN?
Prismasol B0 is presented in a two compartment bag containing in the smaller compartment A, the electrolyte solution, and in the larger compartment B, the buffer solution. The final reconstituted solution is obtained after breaking the peel seal and mixing both solutions.

Before reconstitution
1000 ml of electrolyte solution **(small compartment A)** contains:

Calcium chloride, 2 H_2O	5.145 g
Magnesium chloride, 6 H_2O	2.033 g
Lactic acid	5.4 g
Water for injections	to 1000 ml

1000 ml of buffer solution **(large compartment B)** contains:

Sodium hydrogen carbonate	3.09 g
Sodium chloride	6.45 g
Water for injections	to 1000 ml

After reconstitution
The solution in the small and the large compartments are mixed to give one reconstituted solution whose composition is:

	mmol/l	mEq/l
Calcium, Ca^{2+}	1.75	3.50
Magnesium, Mg^{2+}	0.5	1.0
Sodium, Na^{+}	140	140
Chloride, Cl^{-}	109.5	109.5
Lactate	3	3
Hydrogen carbonate, HCO_3^{-}	32	32

Theoretical Osmolarity: 287 mOsm/l

PACKAGING:
2 bags (5000 ml) per carton

NAME AND ADDRESS OF MANUFACTURER:
Bieffe Medital S.p.A.
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Italy

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Chennai 600060 TAMILNADU

WHAT IS PRISMASOL B0 AND WHAT IS IT USED FOR?
Prismasol B0 is a solution for haemofiltration, haemodiafiltration and continuous haemodialysis. The processes of haemofiltration and continuous haemodialysis aim at normalising the composition of the blood.
Prismasol B0 is a solution packed in a two compartment bag. The electrolyte solution (in the small compartment A) must be mixed with the buffer solution (in the large compartment B) before use to obtain the final solution suitable for the treatment.
Prismasol B0 is used in the treatment of acute kidney disease (renal failure), as substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis. Prismasol B0 may also be used in case of drug poisoning with dialysable or filterable substances.
Prismasol B0 is particularly indicated when you are suffering from high potassium level in your blood (hyperkalaemic).

BEFORE YOU USE PRISMASOL B0
The instructions for use should carefully be followed.
Do not use Prismasol B0 if you are allergic to one of the active substances or any of the other ingredients.

WARNINGS AND PRECAUTIONS
Talk to your doctor, pharmacist or nurse before using Prismasol B0.
Prismasol B0 is a product to be used in hospitals and administered by medical professionals only. They will ensure a safe use of the medicine.
Before and during treatment, your blood condition will be checked, e.g. your acid-base balance and concentrations of salts in the blood (electrolytes) will be monitored, including all fluid you are given (intravenous infusion) and that you produce (urine production), even those not directly related to the therapy.
As the solution is potassium free, special attention should be given to potassium levels. Phosphate substitution and potassium supplement might be necessary.
Do not use with a haemodialysis monitor. You should only use monitors for Continuous Renal Replacement Therapies.

PREGNANCY AND LACTATION
You must tell your doctor if you are pregnant or intend to become pregnant.

EFFECT ON ABILITY TO DRIVE AND USE MACHINERY
Not relevant.

INTERACTION WITH OTHER MEDICINES
The blood concentration of filterable/dialysable drugs may be reduced during treatment. Corresponding corrective therapy should be instituted if necessary to establish the desired blood concentrations for drugs removed during treatment.
Interactions with other medications due to electrolyte and/or acid-base imbalances can be avoided by correct dosage of the solution for haemofiltration and haemodialysis and precise monitoring.
However, the following interactions are conceivable:

- The risk of digitalis-induced cardiac arrhythmia is increased during hypokalaemia;
- Vitamin D and medicinal products containing calcium, e.g. calcium carbonate as phosphate binder, can increase the risk of hypercalcaemia;
- Additional sodium bicarbonate substitution (or other buffer source) may increase the risk of metabolic alkalosis.
- When citrate is used as an

anticoagulant, it can reduce plasma calcium levels.

HOW SHOULD YOU USE PRISMASOL B0?

Prismasol B0 is to be used only by or under the direction of a physician competent in intensive care treatment using haemofiltration, haemodiafiltration and haemodialysis.

Prismasol B0 should be used only if the solution is clear, the overwrap is not damaged, peel seal is not broken and all seals are intact.

INSTRUCTION FOR USE/ HANDLING

I Remove the overwrap from the bag immediately before use and discard any other packaging materials. Open the peel seal by holding the small compartment with both hands and squeeze it until an opening is created in the peel seal between the two compartments. (See figure I below)

II Push with both hands on the large compartment until the peel seal between the two compartments is entirely open. (See figure II below)

III Secure complete mixing of the solution by shaking the bag gently (See figure III below). The solution is now ready for use, and can be hung on the equipment.

IV The dialysis or replacement line may be connected to either of the two access ports.

IV.a If the luer access is used, remove the cap with a twist and pull motion, and connect the male luer lock on the dialysis or replacement line to the female luer receptor on the bag using a push and twist motion. Ensure that the connection is fully seated and tighten. The connector is now open. Verify that the fluid is flowing freely. (See figure IV.a below) When the dialysis or replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop. The luer port is a needle-less and swabbable port.

IV.b If the injection port is used, first remove the snap-off cap. Then introduce the spike through the rubber septum. Verify that the fluid is flowing freely. (See figure IV.b below)

IF YOU USE MORE PRISMASOL B0 THAN YOU SHOULD

Prismasol B0 is a product to be used in hospitals and administered by medical professionals only and your fluid balance, electrolyte and acid-base balance will be carefully monitored.

Therefore, it is unlikely that you will use more PRISMASOL B0 than you should.

In the unlikely event that an overdose occurs, your doctor will take necessary corrective measures and adjust your dose.

Overdose may result in:

- fluid overload in your blood,
- elevation of the bicarbonate blood level (metabolic alkalosis),
- and/or reduction of levels of salts in the blood (hypophosphataemia, hypokaliemia).

WHAT SIDE EFFECTS CAN PRISMASOL B0 CAUSE?

When haemofiltration, haemodiafiltration and continuous haemodialysis are performed correctly, side effects are uncommon. The content of the fluid is similar to that of blood and the quantity of fluid used is controlled.

Some side effects may occur, especially when too much fluid is removed from your body, these include:

- Changes of levels of salts in the blood (electrolyte imbalances such as hypophosphataemia, hypokalaemia)
- Elevation of the plasma bicarbonate concentration (metabolic alkalosis) or reduction of the plasma bicarbonate concentration (metabolic acidosis)
- Abnormally high or low volume of water in the body (hyper or hypovolemia)
- Nausea
- Vomiting
- Muscle cramps
- Low blood pressure (hypotension)

If you suffer from any of these side effects or any other undesired side effect, please inform your doctor or nurse immediately.

STORAGE AND EXPIRY DATE OF PRISMASOL B0

Keep Prismasol B0 out of reach and sight of children.

Do not use Prismasol B0 after the expiry date shown on the label and the packaging.

Use only if the solution is clear. Press bag firmly to test for any leakage. If leakage is discovered, discard the solution immediately since sterility can no longer be assured.

Do not store below +4°C.

In use stability has been demonstrated for 24 hours after reconstitution.

From a microbiological point of view, once opened (i.e. connected to the line), the product should be used immediately. Other in-use storage times and conditions are the responsibility of the user and would not normally be longer than 24 hours, including the duration of the treatment, as hydrogen carbonate is present.

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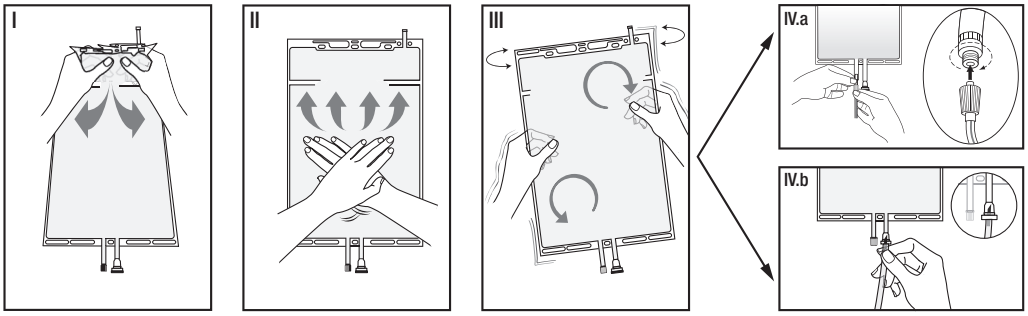

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