UK, IE, MT Package leaflet: Information for the user

Hemosol B0 solution for haemodialysis/haemofiltration

Sodium chloride/calcium chloride dihydrate/magnesium chloride hexahydrate/ lactic acid/sodium hydrogen carbonate.

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.
- 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.

WHAT IS IN THIS LEAFLET

1. WHAT HEMOSOL B0 IS AND WHAT IT IS USED FOR

Hemosol B0 is used in hospitals in intensive care treatments to correct chemical imbalance of the blood which is caused by kidney failure. The treatments are designed to remove accumulated waste products from the blood when the kidneys are not functioning.

Hemosol B0 is used in the following types of treatment in adult and children of all ages:

- haemofiltration,
- haemodiafiltration and
- haemodialysis.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HEMOSOL B0

DO NOT USE HEMOSOL B0:

If you are allergic to one of the active substances or any of the other ingredients (listed in section 6).

WARNINGS AND PRECAUTIONS

Talk to your doctor, pharmacist or nurse before using Hemosol B0. Hemosol 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 Hemosol B0 is potassium-free, special attention will be given to the level of potassium in your blood. Should you suffer from low potassium a potassium supplement might be necessary.

CHILDREN

There are no specific warnings and precautions when using this medicine for children.

OTHER MEDICINES AND HEMOSOL B0

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is because the concentration level in the blood of some of other medicines being taken may be reduced during the treatment with Hemosol B0. Your doctor will decide if other medicines being taken should be changed.

In particular tell your doctor if you are using either of the following:

- Digitalis medicine (for treatment of certain heart conditions); as the risk of irregular or rapid beating of the heart (cardiac arrhythmia) caused by digitalis is increased during a low concentration of potassium in the blood (hypokalaemia).
- Vitamin D and medicinal products containing calcium, as they can increase the risk of a high concentration of calcium in the blood (hypercalcaemia).

Any addition of sodium bicarbonate (or other buffer source) may increase the risk of excess of bicarbonate in your blood (*metabolic alkalosis*).

When citrate is used as an anticoagulant, it can reduce plasma calcium levels.

PREGNANCY, BREASTFEEDING AND FERTILITY

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

No effects on fertility or during pregnancy or on the breast-fed newborn/infant are anticipated. Your doctor will decide if you should be given Hemosol B0 if you are pregnant or breast-feeding.

DRIVING AND USING MACHINES

Hemosol B0 will not have any effect on the ability to drive or use machines.

3. HOW TO USE HEMOSOL B0

Hemosol B0 is a product to be used in hospitals and administered by medical professionals only.

The volume of Hemosol B0, and therefore the dose used, will depend on your condition. The dose volume will be determined by the physician responsible for your treatment.

Hemosol B0 can be administered directly into the bloodstream (intravenously) or via haemodialysis, where the solution flows on one side of a dialysis membrane while the blood flows on the other side.

IF YOU USE MORE HEMOSOL B0 THAN YOU SHOULD

Hemosol 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 Hemosol 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, hypokalaemia).

For instructions for use, please see section “The following information is intended for healthcare professionals only”.

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, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

Not known: frequency cannot be estimated from the available data

- 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 hypovolaemia)
- Nausea
- Vomiting
- Muscle cramps
- Low blood pressure (hypotension).

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:

Malta:

ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

Republic of Ireland:

HPRA Pharmacovigilance Earlsfort
Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

United Kingdom:

Yellow Card Scheme
www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE HEMOSOL B0

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 back of the bag and the box label after EXP. The expiry date refers to the last day of that month.

Do not store below 4°C.

Chemical and physical in-use stability of the reconstituted solution has been demonstrated for 24 hours at 22°C. From a microbiological point of view, the reconstituted solution should be used immediately. If not used immediately in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 24 hours including the duration of the treatment.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

WHAT HEMOSOL B0 CONTAINS

The active substances before and after reconstitution are shown below.

ACTIVE SUBSTANCES BEFORE RECONSTITUTION:

1000 ml of solution **from the small compartment (A)** contains:

Calcium chloride, $2H_2O$	5.145 g
Magnesium chloride, 6 H_2O	2.033 g
Lactic acid	5.4 g

1 000 ml of solution **from the large compartment (B)** contains:

Sodium hydrogen carbonate	3.09 g
Sodium chloride	6.45 g

ACTIVE SUBSTANCES AFTER RECONSTITUTION:

The solutions in the compartments A (250 ml) and B (4750 ml) are mixed to give one reconstituted solution (5000 ml) which composition is:

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

Theoretical Osmolarity: 287 mOsm/l

The other ingredients are: carbon dioxide (E 290) and water for injections.

WHAT HEMOSOL B0 LOOKS LIKE AND CONTENTS OF THE PACK

Hemosol B0 is presented in a two-compartment bag. The bag is overwrapped with a transparent film.

The final reconstituted solution is obtained after breaking the peel seal and mixing both solutions.

The reconstituted solution is clear and colourless. Each bag (A+B) contains 5000 ml solution for haemofiltration, haemodiafiltration and/or haemodialysis.

Each box contains two bags and one package leaflet.

MARKETING AUTHORISATION HOLDER:

United Kingdom:

Baxter Healthcare Ltd,
Caxton Way,
Thetford, Norfolk,
IP24 3SE,
United Kingdom

Republic of Ireland and Malta:

Baxter Holding B.V.
Kobaltweg 49
3542 CE Utrecht
Netherlands

MANUFACTURER:

Baxter Healthcare S.A.
Moneen Road,
Castlebar, Co. Mayo F23 XR63
Ireland

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom (Northern Ireland): Hemosol B0.

This leaflet was last revised in 03/2023

UK, IE, MT The following information is intended for healthcare professionals only

Hemosol B0 solution for haemodialysis/haemofiltration

PRECAUTIONS

The instructions for use / handling for Hemosol B0 must be strictly followed.

The solutions in the two compartments **must** be mixed **before use**.

Use of a contaminated solution may cause sepsis, shock and fatal conditions.

Hemosol B0 may be warmed to 37°C to enhance patient comfort. Warming of the solution prior to use should be done before reconstitution with dry heat only. Solutions should not be heated in water or in a microwave oven. The solution should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer unless the solution is clear and the seal is intact.

Additional sodium bicarbonate substitution may increase the risk of metabolic alkalosis.

Before and during treatment, electrolyte and acid-base balance should be closely monitored.

As Hemosol B0 is potassiumfree, the serum potassium concentration must be monitored before and during haemofiltration and/or haemodialysis. Potassium supplement might be necessary.

Phosphate up to 1.2 mmol/L may be added to the solution. If potassium phosphate is added, the total potassium concentration should not exceed 4 mEq/L (4 mmol/L).

The volume and rate at which Hemosol B0 is used will depend on the blood concentration of electrolytes, acid-base balance, and overall patient's clinical condition. Administration (dose, infusion rate and cumulative volume) of Hemosol B0 should be established by a physician. Continued application of haemofiltration will remove excess fluid and electrolytes.

In case of fluid imbalance, the clinical situation must be carefully monitored and fluid balance should be corrected as needed.

Overdose will result in fluid overload if the patient is suffering from renal failure, and it could lead to severe consequences, such as congestive heart failure, electrolyte or acid-base disturbances.

Because the solution contains no glucose, administration may lead to hypoglycaemia. Blood glucose levels should be monitored regularly.

Hemosol B0 contains hydrogen carbonate (bicarbonate), and lactate (a hydrogen carbonate precursor) which can influence the patient's acid-base balance. If metabolic alkalosis develops or worsens during therapy with the solution, the administration rate may need to be decreased, or the administration stopped.

POSOLOGY

Commonly used flow rates for the substitution solution in haemofiltration and haemodiafiltration are: Adult 500-3000 mL/h

Commonly used flow rates for the dialysis solution (dialysate) in continuous haemodialysis are: Adult 500-2500 mL/h

Commonly used flow rates in adults are approximately 2000 to 2500 ml/h which correspond to a daily fluid volume of approximately 48 to 60 L.

PAEDIATRIC POPULATION

The range of flow rates for the substitution solution in haemofiltration and haemodiafiltration and for the dialysis solution (dialysate) in continuous haemodialysis are:
Children (from neonates to adolescents to 18 years): 1000 to 2000 ml/h/1.73m^2.

Flow rates up to 4,000 mL/h/1.73 m^2 may be needed, especially in younger children (≤10 kg). The absolute flow rate (in mL/h) in the paediatric population should generally not exceed the maximum adult flow rate.

INSTRUCTION FOR USE / HANDLING

The electrolyte solution (small compartment A) is added to the buffer solution (large compartment B) after opening the peel seal immediately before use to obtain the reconstituted solution.

Use only with appropriate extracorporeal renal replacement equipment.

Aseptic technique should be used throughout the handling and administration to the patient.

Use only if the overwrap is undamaged, all seals are intact, peel seal is not broken and 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.

The large compartment B is fitted with an injection port for the possible addition of other necessary drugs after reconstitution of the solution. It is the responsibility of the physician to judge the compatibility of an additive medication with Hemosol B0 by checking for eventual colour change and/ or eventual precipitation, insoluble complexes or crystals. Before adding a medication, verify it is soluble and stable in water within the pH limits of Hemosol B0 (pH limits of reconstituted solution is 7.0 to 8.5). Additives may be incompatible.

The Instructions for Use of the medication to be added must be consulted.

Remove any fluid from the injection port, hold the bag upside down, insert the drug through the injection port and mix thoroughly. The solution must be administered immediately.

The introduction and mixing of additives must always be performed prior to connecting the solution bag to the extracorporeal circuit.

I. Remove the overwrap from the bag immediately before use and discard any other packaging materials. Open the 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. The solution is now ready for use and the bag can be hung on the equipment. (See figure III below)

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)

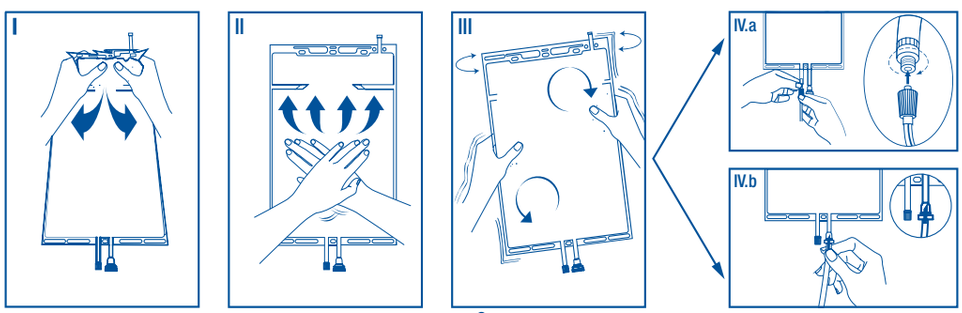
When the dialysis or replacement line is disconnected from the luer connector, the connector will close and the flow of the solution will stop. The luer port is a needle-less and swabbable port.

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

The solution should be used immediately after removal of the overwrap. If not used immediately, the reconstituted solution should be used within 24 hours, including the duration of the treatment after addition of the electrolyte solution to the buffer solution.

The reconstituted solution is for single use only. Discard any unused solution immediately after use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.



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