

# Hemosol B0

Bicarbonate - Buffered Solution  
for Continuous Hemodialysis,  
Hemofiltration and Hemodiafiltration



	mmol/l	mEq/l
Sodium Na+	140	140
Potassium K+	0	0
Calcium Ca2+	1.75	3.50
Magnesium Mg2+	0.5	1.0
Chloride Cl-	109.5	109.5
Hydrogen carbonate HCO3-	32	32
Lactate-	3	3
Glucose	0	



# Hemosol B0 – Summary of product characteristics

## 1. Name of the medicinal product

Hemosol B0, solution for hemofiltration and hemodialysis.

## 2. Qualitative and quantitative composition

Hemosol B0 consists of a two compartment PVC bag containing the electrolyte solution in the small compartment (compartment A) and the buffer solution in the large compartment (compartment B).

### Before reconstitution

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

#### active substances:

Calcium chloride, 2H <sub>2</sub> O	5.145 g
Magnesium chloride, 6H <sub>2</sub> O	2.033 g
Lactic acid	5.400 g

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

#### active substances:

Sodium hydrogen carbonate	3.090 g
Sodium chloride	6.450 g

For excipients see 6.1

### After reconstitution

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

	in mmol/l	in mEq/l
Calcium Ca <sup>2+</sup>	1.75	3.50
Magnesium Mg <sup>2+</sup>	0.5	1.0
Sodium Na <sup>+</sup>	140	140
Chloride Cl <sup>-</sup>	109.5	109.5
Lactate	3	3
Hydrogen carbonate HCO <sub>3</sub> <sup>-</sup>	32	32

Theoretical Osmolarity: 287 mOsm/l

## 3. Pharmaceutical form

Solution for hemofiltration and hemodialysis.

Clear and colorless reconstituted solution.

## 4. Clinical particulars

### 4.1 Therapeutic Indications

As substitution solution in continuous hemofiltration and hemodiafiltration and as dialysis solution in continuous hemodialysis for acute renal failure.

### 4.2 Posology and method of administration

#### Posology:

The volume of substitution solution to be administered will depend on the intensity of the treatment performed and on the amount of solution which has to be replaced in order to achieve the target fluid balance. The dose volume is therefore at the discretion of the responsible physician.

Commonly used flow rates for the substitution solution in hemofiltration and hemodiafiltration are:

Adult: 500 - 1500 ml/hour

Children: 15 - 20 ml/kg/hour

Commonly used flow rates for the dialysis solution (dialysate) in continuous hemodialysis are:

Adult: 500 - 2000 ml/hour

Children: 15 - 20 ml/kg/hour

#### Method of administration:

Hemosol B0, when used as a substitution solution is administered into the circuit before (pre-dilution) or after the hemofilter (post-dilution).

### 4.3 Contra-indications

There are no absolute contra indications to the use of Hemosol B0.

### 4.4 Special warnings and special precautions for use

#### Warnings:

The substitution solution Hemosol B0 is potassium-free.

Check that the solutions are clear and that all seals are intact before mixing.

Carefully follow the instructions for use.

The electrolyte solution **must** be mixed with the buffer solution **before use** to obtain the final solution suitable for hemofiltration/ hemodiafiltration/continuous hemodialysis.

Do not administer the solution unless it is clear. Aseptic technique must be used during connection / disconnection of the line sets.

When used with a monitor, only monitors for Continuous Renal Replacement Therapies must be used. Do not use with a hemodialysis monitor.

#### Special precautions for use:

The heating of this substitution solution to body temperature (37°C) must be carefully controlled.

Before and during treatment, hemodynamic status, fluid balance, electrolyte and acid-base balance should be closely monitored throughout the procedure.

Special attention should be given to potassium levels. Phosphate substitution and potassium supplement might be necessary.

The use of contaminated hemofiltration solution may cause sepsis, shock and fatal conditions.

### 4.5 Interaction with other medicinal products and other forms of interaction

The blood concentration of filterable/dialysable drugs may be reduced during treatment. Corresponding corrective therapy should be instituted if necessary. Interactions with other medications due to electrolyte and/or acid-base imbalances can be avoided by correct dosage of the solution for hemofiltration and hemodialysis and precise monitoring.

However, the following interactions are conceivable:

- The risk of digitalis-induced cardiac arrhythmia is increased during hypokalemia;
- Vitamin D and medicinal products containing calcium, e.g. calcium carbonate as phosphate binder, can increase the risk of hypercalcaemia;
- Additional sodium bicarbonate substitution may increase the risk of metabolic alkalosis.

### 4.6 Pregnancy and lactation

There are no adequate data from the use of Hemosol B0 in pregnant or lactating women. The prescriber should consider the benefit/risk relationship before administering Hemosol B0 to pregnant or breast-feeding women.

### 4.7 Effects on ability to drive and use machines

Not relevant

### 4.8 Undesirable effects

Some undesirable effects related to the dialysis treatment can occur, such as nausea, vomiting, muscle cramps and hypotension.

Electrolyte disturbances may occur. Special attention must be taken for patients with

hypokalemia as this solution is potassium-free (see section 4.4 Warnings and precautions for use).

### 4.9 Overdose

Overdose with Hemosol B0 substitution fluid should not occur if the procedure is carried out correctly and the fluid balance, electrolyte and acid-base balance of the patient are carefully monitored.

However, overdose will result in fluid overload in patients with renal failure.

Continued application of hemofiltration will remove excess fluid and electrolytes.

In case of hyper hydration, the ultrafiltration must be increased and the rate of administration of the solution for hemofiltration reduced. In the case of a severe dehydration it is necessary to cease ultrafiltration and to increase the inflow of solution for hemofiltration appropriately.

Overdose could lead to severe consequences, such as congestive heart failure, electrolyte or acid-base disturbances.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group: Hemofiltrates. ATC code: B052B**

Hemosol B0 is pharmacologically inactive. The sodium, calcium, magnesium and chloride ions are present at concentrations similar to physiological levels in plasma.

The solution is used to replace water and electrolytes removed during hemofiltration or to serve as a suitable exchange medium for use during hemodiafiltration or continuous hemodialysis.

Bicarbonate is used as an alkalizing buffer.

### 5.2 Pharmacokinetic properties

Not relevant. The active ingredients are pharmacologically inactive and are present at concentrations similar to physiological plasma levels.

### 5.3 Preclinical safety data

Not relevant. The active ingredients are pharmacologically inactive and are present at concentrations similar to physiological plasma levels.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

**In the small compartment A:** Water for injections

**In the large compartment B:** Water for injections, Carbon dioxide.

### 6.2 Incompatibilities

In the absence of compatibility studies, this product must not be mixed with other medicinal products.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Hemosol B0 solution by checking for eventual color change and/or eventual precipitation, insoluble complexes or crystals. The Instructions for Use of the medication to be added must be consulted. Before adding a drug, verify it is soluble and stable in water at the pH of Hemosol B0 (pH of reconstituted solution is 7.0 to 8.5). The compatible medication must be added to the reconstituted solution and the solution must be administered immediately.

### 6.3 Shelf life

1 year as packaged for sale.

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

### 6.4 Special precautions for storage

Do not store below +4°C.

### 6.5 Nature and contents of container

The container made in Poly(vinyl) chloride (PVC) is a two compartment bag (250 ml + 4750 ml). A frangible pin separates the two compartments. The large compartment B (4750 ml) is fitted with an injection port for drug's admixture after reconstitution of the solution, as well as a luer connector for the connection of the bag with a suitable substitution fluid / dialyzate line.

The bag is overwrapped with a transparent overpouch made of multi layer copolymers.

Each cardboard box contains two bags.

### 6.6 Instructions for use and handling, and disposal (if appropriate)

The electrolyte solution is added to the buffer solution after breaking the frangible pin and before administration to the patient.

A patient information leaflet with detailed instruction for use is enclosed in the box.

Aseptic technique should be used throughout administration to the patient:

Remove the overwrap from the bag and the sheet between the folded compartments.

If a frangible pin separates the two compartments of the bag the following instructions should be followed:

**I.** Open the seal by breaking the frangible pin between the two compartments of the bag.

The frangible pin will remain in the bag.

**II.** Make sure all the fluid from the small compartment A is transferred into the large compartment B.

**III.** Rinse the small compartment A **twice** by pressing the mixed solution back into the small compartment and then back into the large compartment B.

**IV.** When the small compartment is empty: shake the large compartment B so that the contents mix completely.

The solution is now ready for use. If the luer connector is used, first connect the replacement or dialyzate line and then break the frangible pin in the luer connector.

The bag should hang in all three hanging holes when used.

Connect the substitution fluid/dialyzate line.

Should be used immediately or within 24 hours after addition of the electrolyte solution to the buffer solution. The reconstituted solution is for single use only. Do not use if container is damaged or if solution is not clear. Discard any unused solution.

## 7. Marketing authorization holder

Gambro Lundia AB - Box 10 101 - SE-220 10 Lund - SWEDEN.

## 8. Marketing authorization number

Austria: Zul. Nr. 1-23331; Belgium: AUT 6000 IE33 F2; Denmark: MT. nr. 30456;

Finland: MT. nr. 13902; France: 351 782-1; Germany: Zul. nr. 45140-00-00;

Greece: 2265/11-4-2005; Ireland: PA 785/5/1; Portugal: 3893088; Spain: 851022.1;

Sweden: MT. nr. 14104; Switzerland: 56202001; The Netherlands: RVG 23960;

United Kingdom: PL 14983/0012.

## 9. Date of first authorization/Renewal of the authorization

## 10. Date of Revision of the Text

2006-05-05

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