



Information for use – Please read carefully!



AMINAL®-SET AD 0255

for preparation of acidic concentrated solution for bicarbonate haemodialysis

COMPOSITION

AMINAL® - SET AD 0255 consists of:

- **Solid components**
 - Sodium chloride (NaCl)
 - Glucose (C₆H₁₂O₆·H₂O)
- **Liquid concentrate**
 - Potassium chloride (KCl)
 - Calcium chloride (CaCl₂·2H₂O)
 - Magnesium chloride (MgCl₂·6H₂O)
 - Acetic acid (CH₃COOH)

1 l liquid concentrate contains:

Potassium chloride	KCl	52.180 g
Calcium chloride	CaCl ₂ ·2H ₂ O	77.180 g
Magnesium chloride	MgCl ₂ ·6H ₂ O	35.570 g
Acetic acid	CH ₃ COOH	63.050 g

INSTRUCTIONS FOR USE

100 l acidic concentrated solution for bicarbonate haemodialysis (1 + 34) is prepared by mixing:

NaCl	21.500 kg
Liquid concentrate	10 l
C ₆ H ₁₂ O ₆ ·H ₂ O	3.850 kg
Purified water	to 100 l

Prepared acidic concentrated solution is used in combination with alkaline solution of 8.4% NaHCO₃ and purified water in the following ratio:

1	+	1.225	+	32.775
----------	----------	--------------	----------	---------------

1 l of the diluted solution (1+1.225+32.775) contains:

Na ⁺	140.000 mmol
K ⁺	2.000 mmol
Ca ⁺⁺	1.500 mmol
Mg ⁺⁺	0.500 mmol
CH ₃ COO ⁻	3.000 mmol
Cl ⁻	111.000 mmol
HCO ₃ ⁻	32.000 mmol
Glucose (1 g/l)	5.550 mmol

Prepared ready to use solution is sufficient for a dialysis session that lasts approximately 4-6 hours based on a dialysate flow rate of 500 ml/min and a sodium bicarbonate concentration of 35 mmol/L.

Conductivity of mixed diluted solution: 13.5 [mS/cm] at 25°C.

Osmolarity of mixed diluted solution: 298 mOsm/l.

Neither the concentrated nor the diluted solutions should be injected!

Ready-to-use bicarbonate haemodialysis solution

Unless otherwise prescribed, mix alkaline and acidic bicarbonate haemodialysis concentrate with water of a suitable grade as directed to produce ready-to-use bicarbonate haemodialysis solution (See Instruction for use, Package leaflets for AMINAL®).

Freshly distilled water obtained under sterile conditions is the preferred medium for the dilution of bicarbonate haemodialysis concentrates.

However, purified water (aqua purificata) may also be used if it meets the microbiological requirements of tap water and complies with the notes below. If the water is deionised, special attention must be paid to the possible presence of pyrogens.

Notes: Tap water is not suitable for the preparation of bicarbonate haemodialysis solutions.

If purified water (aqua purificata) is used, particularly in the cases of repeated haemodialysis, it is necessary to be aware of the possible presence of trace amounts of water treatment residuals or chemical elements.

In particular, it is recommended that the aluminum, tin, mercury, zinc, fluoride, phosphate and sulphate levels in the water are closely monitored and a maximum aluminium concentration of 10 µg/l should not be exceeded. It is also desirable for the water used for haemodialysis not to contain any free chlorine and ozone.

INDICATIONS

AMINAL®-SET AD 0255 is used for preparation of acidic concentrated solution for bicarbonate haemodialysis. Haemodialysis is indicated for treatment of the following: kidney insufficiency or failure (acute and chronic); acute intoxication/poisoning with small molecular weight dialyzable substances; and various conditions of metabolism disturbance of water and electrolytes.

During haemodialysis, ion exchange between the patient's blood and dialysis liquid is conducted through a semi-permeable membrane. Concentration gradients of solute between the blood and dialysis fluid lead to the desired changes in the patient's serum solutes, eliminating or reducing concentrations of urea, proteins and other substances and leading to an equilibrium of Na, Cl, K and Mg ions. Permeation of water into the organism can be prevented by altering the hydrostatic pressure.

POSSIBLE SIDE EFFECTS

During haemodialysis the following adverse effects may occur: sickness, vomiting, muscle spasm, headache, hemodynamic imbalance (rise or fall in blood pressure) cardiac arrhythmia, and disturbed hematopoiesis.

CAUTION

Do not use **AMINAL®-SET AD 0255** after the expiry date which is stated on the packaging (abbreviation used for expiry date). The expiry date refers to the last day of that month.

Do not use the concentrate if the packaging is damaged in any way.

Do not use the concentrate if the solution appears cloudy.

Open packaging immediately before preparing the acidic concentrated solution.

The concentrate should be used within 12 hours after first opening. Discard any remaining unused concentrate.

The concentrate is for single use only.

User is responsible for preparing and storing acidic haemodialysis solution according to instructions given by the manufacturer of dissolution mixing unit (equipment). User is obliged to further use prepared acidic concentrated solution only if it complies with the quality requirements defined by the manufacturer of **AMINAL®-SET AD 0255**.

Keep out of the reach of children!

When setting up or disconnected, pay attention to the directions for the relevant haemodialysis monitor, as described in their manual instruction.

The concentrated solutions for haemodialysis can be used with all haemodialysis monitors made by all world known manufacturers.

The concentrated solutions for haemodialysis are used only in specialized stationary health institutions for haemodialysis.

In order not to endanger the life of the patient, dialysis treatment should be carried out by qualified personnel, i.e. individuals who can operate and are familiar with the instructions for the use of the relevant haemodialysis monitor. Qualified personnel must provide regular inspection of containers/bottles and hemodialysis equipment along with monitoring of dialysis treatment.

The concentrate is non-pyrogenic.

The concentrate is not sterile.

STORAGE

Store at a temperature from 5°C to 25°C.

PACKAGING

Collective cardboard box containing: canister (HDPE) with 10 l liquid concentrate, two bags (LDPE) with 10.750 kg sodium chloride in secondary cardboard packaging and bag (LDPE) with 3.850 kg glucose.

Read instructions carefully before using AMINAL®-SET AD 0255!



Use by



Lot number

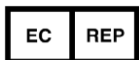


Single use only/
Do not re-use/
Discard any unused solution



ALKALOID AD Skopje
Blvd. A. Makedonski 12
1000 Skopje
Republic of North Macedonia

Manufacturer:



ALKALOID-INT d.o.o.
Šlandrova ulica 4
1231 Ljubljana-Črnuče
R Slovenija

Authorised Representative in the European Community: