Information for use – Please read carefully!

0344 ALKALOID SKOPJE

AMINAL®-C1,5D 0,50/3-1,25
ACIDIC
CONCENTRATED SOLUTION FOR BICARBONATE HAEMODIALYSIS

COMPOSITION

1L of the concentrated solution contains:

270.883 g	Sodium chloride	(NaCl)	4635.000 mmol
10.064 g	Potassium chloride	(KCl)	135.000 mmol
8.269 g	Calcium chloride	($CaCl_2 \cdot 2H_2O$)	56.250 mmol
4.574 g	Magnesium chloride	($MgCl_2 \cdot 6H_2O$)	22.500 mmol
8.107 g	Acetic acid	(CH_3COOH)	135.000 mmol
74.239 g	Glucose	($C_6H_{12}O_6 \cdot H_2O$)	374.625 mmol

INSTRUCTIONS FOR USE

The concentrated solution should be diluted immediately before use:
Add 42.425L of purified water to 1L of the concentrated solution.
1L of the diluted solution (42.425+1+1.575) contains:

Na^+		138.000 mmol
K^+		3.000 mmol
Ca^{++}		1.250 mmol
Mg^{++}		0.500 mmol
CH_3COO^-		3.000 mmol
Cl^-		109.500 mmol
HCO_3^-		32.000 mmol
Glucose	(1.5 g/l)	8.325 mmol

Acidic concentrated solution AMINAL®-C1,5D 0,50/3-1,25 should be used in combination with dry bicarbonate powder in capsule or with 1.575L appropriate alkaline solution AMINAL®-M ($NaHCO_3$ 8.4% solution).
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: 297 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 Instructions 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 concentrate 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®-C1,5D 0,50/3-1,25 is used in bicarbonate haemodialysis. Haemodialysis is indicated for treatment of the following: kidney insufficiency or failure (acute and chronic); acute intoxication/poisoning with small molecular weight dializable 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 patients 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®-C1,5D 0,50/3-1,25 after the expiry date which is stated on the bottle/canister (abbreviation used for expiry date). The expiry date refers to the last day of that month.
Do not use the concentrated solution if the bottle/canister is damaged in any way.
Do not use the concentrated solution if the solution appears cloudy.
Open bottle/canister immediately before preparing the concentrate.
Dilute alkaline and acidic concentrate for bicarbonate haemodialysis immediately before use.
Packaging of 4.7L, 5L and 6L are for single use only and should be used within 12 (twelve) hours after first opening. Discard any remaining unused solution.
Packaging of 7.8L and 10L may be used for several treatments. Close the canister after every use. Once opened, the product must be used within the following 48 (forty-eight) hours, any remaining unused solution should be discarded appropriately.
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 personal must provide regular inspection of bottles/containers and haemodialysis equipment along with monitoring of dialysis treatment.
The concentrated solution is non-pyrogenic.
The concentrated solution is not sterile.

Storage: Store at a temperature from 5ºC to 25ºC.

Packaging: Canister (PE) containing 10L of concentrated solution.
Canister (PE) containing 7.8L of concentrated solution.
[1)]Bottle (PET) containing 6L of concentrated solution.
[1)]Bottle (PET) containing 5L of concentrated solution.
[1)]Bottle (PET) containing 4.7L of concentrated solution.

Read instructions carefully before using AMINAL®-C1,5D 0,50/3-1,25.

Use by

Lot number

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

[1)]Applicable only for 4.7L, 5L and 6L packaging

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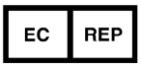

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