Information for use – Please read carefully!

CE 0344 ALKALOID SKOPJE

AMINAL® CITRATE CD/1-1,50
ACIDIC CONCENTRATED SOLUTION FOR BICARBONATE HAEMODIALYSIS

COMPOSITION

1 L of the concentrated solution contains:

276.143 g	Sodium chloride	(NaCl)	4725.000 mmol
3.355 g	Potassium chloride	(KCl)	45.000 mmol
9.923 g	Calcium chloride	($CaCl_2 \cdot 2H_2O$)	67.500 mmol
4.574 g	Magnesium chloride	($MgCl_2 \cdot 6H_2O$)	22.500 mmol
9.454 g	Citric acid	($C_6H_8O_7 \cdot H_2O$)	45.000 mmol
49.493 g	Glucose	($C_6H_{12}O_6 \cdot H_2O$)	249.750 mmol

INSTRUCTIONS FOR USE

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

1 L of the diluted solution (42.425+1+1.575) contains:

Na^+		140.000 mmol
K^+		1.000 mmol
Ca^{++}		1.500 mmol
Mg^{++}		0.500 mmol
$C_3H_5O(COO)_3^{3-}$		1.000 mmol
Cl^-		110.000 mmol
HCO_3^-		32.000 mmol
Glucose	(1 g/l)	5.550 mmol

Acidic concentrated solution citrate based (acetate free) AMINAL® CITRATE CD/1-1,50 should be used in combination with dry bicarbonate powder in capsule or with 1.575 L 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: 14 [mS/cm] at 25^0C
Osmolarity of mixed diluted solution: 294 mOsm/l

Neither the concentrated nor the diluted solutions should be injected!

Ready-to-use bicarbonate haemodialysis solution citrate based (acetate free)
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® CITRATE**).
Freshly distilled water obtained under sterile conditions is the preferred medium for the dilution of bicarbonate haemodialysis concentrates citrate based (acetate free).
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.
Note: Tap water is not suitable for the preparation of bicarbonate haemodialysis solutions citrate based (acetate free).

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 hemodialysis not to contain any free chlorine and ozone.

INDICATIONS
AMINAL® CITRATE CD/1-1,50 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. Citrates are present in low concentration, which does not have a significant effect on the changes in calcium concentration during dialysis treatment, and has a small but significant local anticoagulation effect on the dialyser. Permeation of water into the organism can be prevented by altering the hydrostatic pressure.

BENEFITS
AMINAL® CITRATE CD/1-1,50 is an acidic concentrate for bicarbonate haemodialysis that contains citrates instead of acetates in its composition. Compared to the concentrates for standard bicarbonate haemodialysis which contain acetates, the use of AMINAL® CITRATE CD/1-1,50 has the following benefits:
- anticoagulation effect on dialyser;
- improved acidic-alkaline status;
- less thrombogenic dialysis treatment;
- decreased occurrence of inflammatory processes;
- improved treatment tolerance;
- improved treatment efficacy.

POSSIBLE SIDE EFFECTS
During haemodialysis with citrate based (acetate free) concentrates, the same adverse effects as in standard bicarbonate haemodialysis with acetates may occur, such as: sickness, vomiting, muscle spasm, headache, hemodynamic imbalance (rise or fall in blood pressure), cardiac arrhythmia, and disturbed hematopoiesis.
Signs of hypocalcaemia may occur very rarely during dialysis treatment, with symptoms such as numbness, tingling around the mouth, spasm of the muscles of the hands, unusually long and strong muscle cramps. If any of these symptoms occur, place the haemodialysis apparatus in bypass mode and inform the physician. Symptoms will briefly disappear, due to fast metabolizing of excess citrate. Appearance of other adverse events is not known when citrate based (acetate free) bicarbonate dialysis is properly administered.

CAUTION
Do not use AMINAL® CITRATE CD/1-1,50 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, without additional adjustments.

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

Read instructions carefully before using AMINAL® CITRATE CD/1-1,50.

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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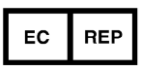
Manufacturer:



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Authorised Representative in the European Community: