Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Kalilactasol, solution for haemofiltration and haemodialysis

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride	5.961	g/l
Calcium Chloride (Dihydrate)	0.257	g/l
Magnesium Chloride (Hexahydrate)	0.152	g/l
Potassium Chloride	0.149	g/l
Sodium Lactate solution 60% w/w	7.471	g/l
corresponding to Sodium Lactate anhydrous	4.483	g/l
Glucose Anhydrous	1.100	g/l
(in Glucose Monohydrate	1.210	g/l)

Kalilactasol solution contains glucose anhydrous 1.1g/litre and in mmol per litre:

Sodium	142.00
Chloride	109.00
Potassium	2.00
Calcium	1.75
Magnesium	0.75
Lactate	40.00

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for haemofiltration and haemodialysis.

Clear solution with a slightly yellow colour.

pH of the solution: 4.5 – 6.5

Theoretical Osmolarity: 301.6 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a substitution solution in continuous haemofiltration and haemodiafiltration and as dialysis solution in continuous haemodialysis and haemodiafiltration for acute renal failure and in cases of drug poisoning with dialysable or filterable substances.

Kalilactasol is particularly indicated in patients who have a tendency to hyperkalaemia.

4.2 Posology and method of administration

Kalilactasol is administered into the venous return of the patient.

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

The volume of the solution administered will depend upon the fluid balance of the individual patient, the target fluid balance to be achieved and the amount of fluid removed from their circulation during the process of haemofiltration.

Dosage will therefore be at the discretion of the Physician.

In continuous haemodialysis or haemofiltration, the clearances obtained are directly proportional to the dialysate flow.

Commonly used flow rates for the substitution solution in haemofiltration and haemodiafiltration are:
Adult: 500 - 1500 ml/hour
Children: 15 - 20 ml/kg/hour

Commonly used flow rates for the dialysis solution in haemofiltration or continuous haemodialysis are:
Adult: 500 - 2000 ml/hour
Children: 15 - 20 ml/kg/hour

Treatment is continued for as long as necessary.

4.3 Contraindications

- hypokalaemia

Lactate based substitution fluids should not be used if the patient has very severe metabolic acidosis or impaired metabolism of lactate.

4.4 Special warnings and precautions for use

The solution is to be used only by or under the direction of a physician who should have a sound experience of intensive care nursing and/or haemofiltration and haemodiafiltration techniques.

The patient’s haemodynamic, fluid, electrolyte and acid-base balance should be closely monitored throughout the procedure. Close monitoring of potassium levels must be carried out to enable the correct selection of the most appropriate potassium concentration.

Severe metabolic acidosis should be corrected with a bicarbonate solution prior to using a lactate based haemofiltration solution.

When used with a monitor, only monitors for Continuous Renal Replacement Therapies must be used.

Do not use with haemodialysis monitor.

Blood glucose concentration should be closely monitored, especially in diabetic patients.

Special attention should be given to patients with severe liver dysfunction, sepsis or heart failure before using lactate based substitution fluids.

4.5 Interaction with other medicinal products and other forms of interaction

Correction of the electrolyte concentration may precipitate symptoms of digitalis excess.

The blood concentration of filterable/dialysable drugs may be reduced during treatment. Corresponding corrective therapy should be instituted if necessary.

4.6 Fertility, pregnancy and lactation

No information is available on the use of this product in pregnancy or lactation.
Administer to pregnant or breast-feeding women only after risk/benefit assessment.

4.7 Effects on ability to drive and use machines

Does not affect the ability to drive or use machinery.

4.8 Undesirable effects

Some undesirable effects related to the dialysis treatment can occur, such as nausea, vomiting, muscle cramps, convulsions and hypotension. Electrolyte disturbance may occur. As the solution contains glucose, especially hyperglycaemia may occur.

4.9 Overdose

Overdose with Kalilactasol Solutions should not occur if the procedure is carried out correctly and the patient's fluid, electrolyte and acid-base balance are monitored closely. However, overdose will result in fluid overload in patients with renal failure. Continued application of haemofiltration will remove excess fluid and electrolytes.
Overdose could lead to severe consequences, such as congestive cardiac failure, electrolyte or acid base disturbances.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Haemofiltrates
ATC code: B05Z B

Kalilactasol is pharmacologically inactive.

In the technique of haemofiltration, plasma water and solutes, including urea, are removed through a semi-permeable membrane, like glomerular filtration in the normal kidney. Because of the large volume of plasma water removed, the process of haemofiltration requires infusion of a sterile substitution solution. Kalilactasol contains sodium, calcium, magnesium, potassium and chloride ions together with glucose at physiological concentrations, which provide a suitable substitution solution.

The lactate is metabolised via Cori cycle on an equimolar basis to bicarbonate, which is required to help correct metabolic acidosis.

The composition of the solution also makes it a suitable exchange medium for use during continuous haemodiafiltration or continuous haemodialysis.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There is no preclinical information that adds to the safety assessment.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections
Hydrochloric acid, 3.646% w/v

6.2 Incompatibilities

Do not mix with bicarbonate containing solution, as this will cause precipitation of calcium and magnesium carbonate.

6.3 Shelf life

2 years.

Shelf life after first opening: for immediate and single use.

6.4 Special precautions for storage

Do not store below +4°C.

6.5 Nature and contents of container

PVC bag.

Pack size: 2 x 5000 ml.

The container features two administrative set ports - one with connector, the other one for spike insertion and drug addition.

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

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Aseptic technique must be used during connection/disconnection of the line sets. The heating of this solution to body temperature must be carefully controlled.

Do not use it the container is damaged or the solution is cloudy. Press firmly on the bag to test for any leakage. If leakage is discovered, discard solution immediately since sterility is no longer guaranteed.

The containers are for single use only. Any unused portion should be discarded.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA0785/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

March 2007