Instructions for use EN

CITRASOL 0.5%
Natrii citras 0.5%

THE SOLUTION IS INTENDED FOR PREVENTION OF BLOOD COAGULATION DURING EXTRACORPOREAL HAEMODIALYSIS.
Anticoagulation solution of sodium citrate 0.5% (Natrii citras 0.5%)

Please, read the following information carefully so you can use the solution in a safe manner.

1.Intended use
The solution CITRASOL 0.5% (Natrii citras 0.5%) is intended for regional anticoagulation in extracorporeal circuit during continuous renal replacement therapy methods.

2. Information about the product
2.1 Product name
CITRASOL 0.5%
Natrii citras 0.5%
medical device class IIb

2.2 Composition of the product
The solution contains sodium citrate dihydrate Ph. Eur. and sodium chloride, Ph. Eur.
pH of the solution is set up using hydrochloric acid, Ph. Eur.

Natrii citras dihydricus	5.29 g
Natrii chloridum	5.03 g
Water for injections	ad 1000 ml

Composition in mmol/l	
Sodium (Na^+)	140
Citrates ($C_6H_5O_7^{3-}$)	18
Chlorides (Cl^-)	86
pH	≈ 6.4 - 7.0
Theoretical osmolarity:	244 mOsmol/l

2.3 Pharmaceutical form of the product
CITRASOL solution 0.5% (Sodium citrate 0.5%) is a sterile clear solution , free from bacterial endotoxins. It is packaged in a transparent multilayer printed bags , which are sealed in plastic wrappers (outer packaging).

2.4 Pharmaceutic group
Anticoagulation solution for whole blood.

3. Therapeutic indication
The solution CITRASOL 0.5% (Natrii citras 0.5%) is intended for whole blood anticoagulation during continuous elimination methods that replace renal function (Continuous Renal Replacement Therapy-CRRT).

4. Contra-indications
There is no absolute contra-indication for the anticoagulation solution CITRASOL 0.5% (Natrii citras 0.5%)
Serious liver function disorder is a relative contra-indication against using citrate anticoagulation. It may cause slow metabolic elimination of the citrate during continuous elimination methods. This disorder may lead to development of metabolic acidosis, hypocalcaemia, or increased demand for calcium substitution. It is necessary in such case to consider termination of the elimination procedure, eventually switching to a different type of elimination method.

5. Undesirable effects
Individuals that receive blood or blood derivative infusion with higher content of citrates may in some cases experience undesirable effects. A significant drop of calcium concentration with following neurological symptoms may occur. The symptoms are: paraesthesia, spasms, and potentially spastic paresis and tetany. As soon as these symptoms appear, it is necessary to stop the infusion, transfusion, or reinfusion or reduce its speed. At the same time it is also required to monitor calcium levels and administer calcium intravenously as the case may be (e.g. calcium gluconate).

6. Instructions for use
The solution CITRASOL 0.5% (Natrii citras 0.5%) is added to blood flowing into the machine (usually venous) with respect to the planned level of anticoagulation. The ratio between the amount of solution and blood is determined by the physician indicating the elimination method. It is usually administered in the ratio of 1 unit of the solution CITRASOL 0.5% (Natrii citras 0.5%) and 3-9 units of whole blood.
For carrying out continuous elimination therapy itself it is necessary to follow the instructions for use issued by the manufacturer of the elimination machine in use.
Amount of the solution CITRASOL 0.5% (Natrii citras 0.5%) used during elimination method must be included into the total fluid balance.

7. Notice
The solution CITRASOL 0.5% (Natrii citras 0.5%) may only be used pre-diluted in machines intended for purposes of continuous renal replacement therapy, furthermore, these machines have to be suitable for usage of regional citrate anticoagulation.
The solution CITRASOL 0.5% (Natrii citras 0.5%) has to be used along with haemodialysis dilution with suitable concentration of bicarbonate.
It is necessary to thoroughly monitor electrolytic (especially calcium, magnesium, and sodium ions) and acid-base balance, fluid balance, and overall hemodynamic condition.

8. Warning
The solution CITRASOL 0.5% (Natrii citras 0.5%)may never be used for direct intravenous infusion.
The solution CITRASOL 0.5% (Natrii citras 0.5%) is for a single use only. Repeated use may lead to transference of infection.
The solution CITRASOL 0.5% (Natrii citras 0.5%) must not be used after its shelf life has expired, the shelf life is printed on the box as well as on the primary packaging of the product.

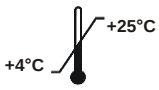
Caution:
It is necessary to remove the external plastic packing only just prior to use of the product.
It is always necessary to check information about solution composition, production batch number, and shelf life.
Use only clear solutions in intact packaging.
Dispose of any non-used up solution.

9. Shelf life and storage conditions
The shelf life of the anticoagulation solution CITRASOL 0.5% (Natrii citras 0.5%) is printed on the packaging.
The solution must not be used after this date.
The solution is stored in temperatures between 4°C and 25°C and protected from light.

10. Type and size of the packaging
PP bags, volume 5000 ml.

11. Information on disposal of the packaging material
Dispose of the packaging material according to legislation in force.

12. Symbols on the package



Storage temperature from +4°C up to +25°C


Follow package information


Used until

Moist heat sterilization


Do not use repeatedly


Manufacturer

Batch number

13. Issue/revision date of the text
13.3.2017

14. Manufacturer
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