CITRASOL 4%
Natrii citras 4%

SOLUTION FOR BLOOD COAGULATION PREVENTION DURING EXTRACORPOREAL BLOOD CLEANSING
Anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%)

Please read the following information carefully to use the solutions safely.

1. Product information
1.1. Product name
CITRASOL 4%
Natrii citras 4%
Medical device, Class IIb

1.2. Product composition
The solution contains sodium citrate dihydrate (Ph. Eur.).
The solution pH is adjusted by means of citric acid monohydrate (Ph.Eur.).

Natrii citras dihydricus	39.7 g
Acidum citricum monohydricum	0.3 g
Aqua pro iniectione	ad 1000 ml

Composition in mmol/l

Na^+	404.6
$C_6H_5O_7^{3-}$	136.4
pH	≈ 7.0

Theoretical osmolarity: 541 mOsmol/l

1.3. Pharmaceutical form of product
The anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) is a sterile clear solution, free from bacterial endotoxins. It is packed in transparent printed PP (polypropylene) bags sealed in plastic packs (secondary pack).

1.4. Pharmaceutical group
Whole blood anticoagulant solution

2. Therapeutic indication
The anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) is intended for whole blood anticoagulation during continuous elimination procedures, used mostly to substitute renal functions (Continuous Renal Replacement Therapy-CRRT). The solution is also intended for aphaeretic and sorptive methods (e.g. haemoperfusion).

3. Instructions for use
Continuous blood cleansing methods: The solution should be added to blood flowing into the device (venous blood usually) depending on the planned anticoagulation level. The ratio of the solution volume to blood quantity should be determined by the physician indicating the elimination method. One part of 4 % sodium citrate dihydrate solution (Natrii citras 4%) to 30-40 parts of whole blood is usually used.
The continuous elimination therapy as such should be performed in accordance with instructions for use provided by the manufacturer of each given elimination device.
The amount of 4 % sodium citrate dihydrate solution (Natrii citras 4%) used during the elimination procedure must be included in the overall fluid balance.

Apheresis procedure by means of a device: The solution should be added to venous blood before apheresis in a ratio ensuring the planned anticoagulation degree. Such ratio must be determined by the physician responsible for the apheresis. One part of the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) to 15 parts of blood is usually used during such procedures.
The apheresis as such should be performed in accordance with instructions for use provided by the manufacturer of each given apheresis device.

Attention:
The outer plastic pack should be removed immediately before the solution use.
Information about composition, production lot number and expiry date of the solution must always be checked.
Clear solutions in undamaged packs may be used only.
All unused solution should be discarded.

3.1. Special warnings and precautions for use
- Special attention must be paid to individuals suffering from blood coagulation impairment. This applies also to people who get transfusion (or reinfusion) of blood or blood derivatives and are treated by anticoagulant substances.

- If the ratio of the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) and whole blood is 1:15 and higher, or if an unusually high speed of reinfusion of blood or blood derivatives treated by the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) is considered, the patient's condition must be monitored closely, at a specialized hospital ward within the reach of an intensive care unit, if possible.
- If the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) is used during the continuous elimination procedures, the physician indicating the therapy must include the quantity of sodium and citrate in the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) in the overall daily balance. Citrates that are not removed from the blood directly during the continuous elimination procedure are metabolized by the patient to bicarbonates. The composition of the used dialysis or substitution solution must take this fact in account.
- If the dialysis or substitution solution used during the continuous elimination therapy contains small amount of calcium, or if it does not contain any calcium at all, calcium loss must be substituted in a corresponding way.
- If the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) is used during a continuous elimination therapy, electrolytes and acid-base balance must be monitored regularly; plasmatic levels of sodium, calcium, magnesium, and bicarbonate should be of particular importance.

4. Contraindications

Severe impairment of liver functions is a relative contraindication of citrate anticoagulation use as it can slow down the metabolic elimination of citrate if continuous elimination procedures are used. Such impairment can cause metabolic acidosis, hypocalcaemia and/or increased need for calcium substitution.

4.1. Interactions with medicinal products and other forms of interaction

No medicinal products may be added into the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%).

5. Undesirable effects

Undesirable effects may appear rarely in some individuals who have been given reinfusion of blood or blood derivatives containing higher amount of citrate. Calcium concentration may drop severely, which may be followed by neurological symptoms. Such symptoms include paraesthesia, convulsions, and potentially even spastic paresis and tetany. As soon as such symptoms appear, the infusion, transfusion or reinfusion must be discontinued or its speed must be reduced.
At the same time, calcium levels must be monitored and, if necessary, calcium must be administered intravenously (e.g. calcium gluconate).

6. Shelf life and storage conditions

The shelf life of the anticoagulant 4 % sodium citrate dihydrate solution (Natrii citras 4%) is shown on the pack. The solution may not be used after the given date expiry.
The solution should be stored under the temperature of from 4°C to 25°C, protected from light.

7. Nature and contents of container

PP bag; volume 1,000 ml and 2,000 ml.

8. Information relating the pack disposal

The pack should be disposed of in accordance with local legislation.

9. Symbols on the package

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


See instructions for use


Used until

Moist heat sterilization


Single use only


Manufacturer

Batch number

10. Date of revision of the text

26.6.2017

11. Manufacturer

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