Product insert

Natrium Citricum 4%
(Trisodium citrate 4%)

SOLUTION FOR APHERESIS AND EXTRACORPOREAL BLOOD PURIFICATION

Anticoagulation solution of trisodium citrate 4%
Read carefully the following information for a safe usage of the solution.

1. Product information:
Product name:
Anticoagulation solution of trisodium citrate 4%

Composition:
One liter of the solution contains trisodium citrate dihydrate Ph. Eur 40 g (4% w/v).
(pH is adjusted with citric acid monohydrate Ph. Eur).
Water for injection Ph. Eur ad 1000 ml.
Ph 6.4-7.5

Pharmaceutical form:
Anticoagulation solution of trisodium citrate 4% is a sterile, pyrogen-free, clear anticoagulation solution filled in transparent printed PP bags. It is delivered in bags of 1000 ml and 2000 ml.

Pharmaceutical group:
Anticoagulation solution for full blood.

2. Treatment indication:
Anticoagulation solution of trisodium citrate 4% is used exclusively for full blood anticoagulation within automated apheresis procedures and continuous methods of blood purification (CRRT – Continuous Renal Replacement Therapy).

3. Important information:
Contraindications:
Severe liver failure represents relative contraindication.

Precautions for usage:
- Not to be administered intravenously
- Not to be used unless the solution is clear
- Check up the bag and safety locks on connection tubings if they are tamper-proof
- Solution shall not be used if the container or outlet safety lock has been tampered
- Residues of the solution have to be disposed of

Interactions with other medical devices and other interactions:
Other medical devices shall not be admixed with anticoagulation solution of trisodium citrate 4%.

Warning and precautions:
- Blood donors with failures of blood coagulation have to be carefully monitored if re-infused with blood or blood segments treated with anticoagulant preparations
- If the ratio Anticoagulation solution of trisodium citrate 4% - Full blood accounts for 1:15 or if unusually high re-infusion rate of acidified blood segments is taken into account, anticoagulation solution of trisodium citrate 4% shall be used very carefully and if possible in specialized hospital centers located near intensive care units.
- If anticoagulation solution of trisodium citrate 4% is used during continuous elimination procedures, physicians indicating renal replacement therapies have to take in consideration a total daily intake of sodium and citrate supplied with anticoagulation solution of trisodium citrate 4%. Citrate which has not been removed directly via renal hemofiltration is metabolized in the body into bicarbonate. This shall be taken into account in compounding the prescribed substitution solution.
- If the substitution solution prescribed for continuous blood purification treatment does not contain calcium or if the calcium assay is lower, it shall be duly replenished.
- If anticoagulation solution of trisodium citrate 4% is used during continuous blood elimination procedures, it is necessary to monitor regularly electrolytes’ levels and acidobasic conditions of the patient blood. Plasmatic sodium, calcium, magnesium and bicarbonate levels can be abnormal above all.

4. Directions for use:
- This preparation is designated for usage with automated apheresis devices and it is added during the depleting phase to venous full blood in the ratio stated according to instructions of the attending physician, typically in the ratio of 1:15 (Anticoagulation solution of trisodium citrate 4% : Full blood).
- The solution is used during continuous blood elimination procedures and it is admixed with venous blood in the ratio stated by the attending physician, as a rule in the ratio of 1:30-40 (Anticoagulation solution of trisodium citrate 4% : Full blood). The bag should be taken out from the wrapping shortly before use.
- Check up the composition, production batch number and expiry date.
- Check up the solution for its clarity.
- Check up the bag and safety locks on connection tubings if tamper-proof. The solution shall not be used if container or outlet safety lock has been tampered.
- Carry out the apheresis procedure in line with detailed operating instructions of the manufacturer of apheresis machines. After anticoagulation solution of trisodium citrate 4% bag has been connected to the apheresis machine, hang it on the relative infusion stand.
- Carry out the continuous hemofiltration according to detailed operating instructions of the manufacturer of dialysis monitors. The amount of anticoagulation solution of trisodium citrate 4% administered via the infusion shall be included in the fluid balance.

5. Adverse reactions:
Adverse reactions may rarely develop in donors that receive a re-infusion with acidified blood or blood segments. These effects are due to presence of the citrate. Adverse reactions to acidified blood portion may develop in patients that receive a re-infusion with blood portion. This reaction is due to the use of anticoagulation solution on a citrate basis. Major side effect developed in patients is paresthesia. If arisen, the re-infusion shall be discontinued or the re-infusion rate shall be decreased. Should an unintentional overdosage of the solution occur, calcium gluconate shall be administered to the patient.

6. Expiry date and way of storage:
Expiry date of anticoagulation solution of trisodium citrate 4% is imprinted on the container’s rear side. The product shall not be used after this date. Anticoagulation solution of trisodium citrate 4% shall be protected from light and stored at the temperature from +4°C to +25°C.

7. Packing: PP bag 1000 ml, 2000 ml

8. Information on packagings’ disposal:
The product is recommended to be considered potentially hazardous waste.

Symbols stated on the container:

Storing temperature: from +4 to +25°C
Caution to follow insert information

Steam sterilization
Pyrogen-free solution

Not to be used repeatedly

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