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Instruction for Anticoagulant Citrate Dextrose Solution(I)

Please read this instruction carefully and use this product under the guidance of physicians.

【Drug Name】

Generic name: Anticoagulant Citrate Dextrose Solution (I)

English name: Anticoagulant Citrate Dextrose Solution (I)

Chinese spelling: Xueye Baocunye (I)

【Composition】

This product is a mixture preparation. 1000 ml of this preparation contains 22.0g ~~sodium citrate~~ ($C_6H_5Na_3O_7 \cdot 2H_2O$), 8.0g ~~citric acid~~ ($C_6H_8O_7 \cdot H_2O$) and 24.5g ~~dextrose~~ ($C_6H_{12}O_6 \cdot H_2O$).

【Description】

This product is a totally or almost colorless and transparent liquid.

【Indications】

Fits for anticoagulation of extracorporeal blood. Primarily used for apheresis of sorts of blood components, such as platelet, plasma, red blood cell, and peripheral blood stem cell.

【Specification】

200ml; 500ml; 1000ml

【Dosage and Administration】

The recommended proportion between this product and extracorporeal whole blood is 1: 8~12.

【Adverse Reactions】

At the normal speed of blood transfusion, this product will not cause obvious adverse reactions. During fast transfusion with large amount of blood conserved with this product, since the citrate could not be oxidized immediately, the recipient might get numbness of mouth and lip, tetany, even the tendency of bleeding, the decrease of blood pressure, ventricle fibrillation or heart arrest, due to the hypocalcemia and metabolic alkalosis.

【Contraindications】

Allergy to this product or ingredients.

【Precautions】

1 When this product is used in the program, extracorporeal circulation is inevitable, which will lead to potential dangers, such as hemolysis and aeroembolism, etc. To prevent any accident, no violation of the operation rules in manuals of corresponding separator is allowed, and uncertificated piping system and other accessories are forbidden to be used.

2 Because the toxication of citrate is ready to appear during fast transfusion with large amount of blood anticoagulated with this product, the speed of back transfusion should be less than 80ml/min. Meanwhile, it is advised to notice the acid base equilibrium, Ca^{++} , and to inspect coagulation function.

3 Caution must be exercised in the case of abnormal level of calcium ions or metabolize abnormality (for example, severe liver injury and kidney disfunction).

4 Never use this product more than once. Before use it, check the transparence of the fluid, and make sure no leakage, mildew or cloudiness in the blood bag. Dispose of the used product.

5 During the separation of blood components, inspect the flow equilibrium of the fluid closely to prevent hypervolemia or hypovolemia.

【Administration of Pregnant and Lactating Women】 Follow the physician's advice.

【Administration of Children】 Follow the physician's advice.

【Administration of the Elder】 Follow the physician's advice.

【Drug Interactions】 Yet to be determined.

【Overdosage】

During fast transfusion with more than 4000ml blood containing sodium citrate, the recipient might get numbness of mouth and lip,

tetany, even the tendency of bleeding (one reason is that this product decrease the tension of capillary vessels which leads to vasoconstriction deficiency), the decrease of blood pressure, ventricle fibrillation or heart arrest. Refer to the text of **【Precautions】** .

【Pharmacology Toxicology】

This product also named ACD-A prescription is blood conserving solution. Ca^{++} is the necessary substance in blood coagulation, which can promote coagulin (coagulation factor III) and the formation of thrombin and fibrin, and activate platelet release reaction to release coagulation factors. The citric acid radical ions in this product react with calcium ions in the blood to produce calcium citrate complex. This complex is soluble in water but difficult to dissociate. It will decrease the calcium ions in the blood, restrain coagulation process and prevent blood coagulation.

Citric acid and sodium citrate compose buffer pair to adjust and stabilize the pH value of solution.

The oxidation metabolism of sodium citrate completes in the circulation of tricarboxylic acid, and the oxidation speed is close to the normal speed of transfusion. The toxication dosage of sodium citrate for the adult is about 15 gram, corresponding to 4000~5000ml blood anticoagulant with sodium citrate. If transfuse slowly, it will be destroyed in the body and eliminated by the kidney. If transfusion speed is too quick or transfusion volume is too large, citrate cannot be oxidized immediately, which will induce the hypocalcemia, and the toxication of citrate will appear.

【Pharmacokinetics】

The toxication dosage of sodium citrate for the adult is about 15 gram, corresponding to 4000~5000ml blood anticoagulant with sodium citrate. Normally, the oxidation metabolism of sodium citrate completes in the circulation of tricarboxylic acid, and the oxidation speed is close to the normal speed of transfusion, and the metabolic products are carbon dioxide and water. If transfuse slowly, sodium citrate will be destroyed in the body and eliminated by kidney.

【Storage】 Seal completely ,and store in cool place.

【Package】

Packing material and container: ~~Soft poly (vinyl chloride) (PVC)~~ blood bags for transfusion.

Packing specification: 200ml、~~500ml~~、 1000ml.

【Validity】 24 months.

【Executive Authorization】 WS-10001- (HD-0610) -2002

【Marketing Authorization Holder、Manufacturer】

Marketing Authorization Holder

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