1.4 Product information

1.4.1 Summary of Product Characteristics

Product name

Product brand name: Sodium Lactate Ringer's Injection

International Nonproprietary name: Sodium Lactate Ringer's Injection

Qualitative and quantitative composition

Each 100ml contain:

Sodium Lactate 0.320g

Sodium chloride 0.600g

Potassium chloride 0.040g

Calcium chloride (CaCl2·dihydrate) 0.027g

Pharmaceutical form

Large volume injection, a colorless solution.

Clinical particulars

Pharmacology and toxicity

In the natural case our blood contain a little lactic acid, it is mainly produced by dextrose or hepatin through zymohydrolysis happening in muscle, skin, brain and cell. After the production of lactate, lactic acid will be translated into hepatin or pyruvic acid, or come into tricabroxylic acid circle, be decomposed to water and carbon dioxide. So the last metabolize production is sodium bicarbonate, it can correct metabolizable acid toxicosis. When the product is indicated for hyperpotassaemia following acidosis, sodium lactate can correct acid toxicosis, and make the potassium come into the cell from blood or extracellular fluid. The main viscera that can decompose lactic acid is liver and kidney. When the metabolize of lactic acid is abnormal or out of gear, the curative effect is not very good.

Indications

It is indicated to adjust the equilibrium of human electrolyte acid and alkali, Used for metabolic acid toxicosis or dehydration caused by metabolic acid toxicosis.

Pharmacokinetics

pH of sodium lactate is 6.5-7.5, it can be absorbed quickly after taking orally , and can be oxidationed by liver in 1-2 hour, with the metabolism products sodium bicarbonate. But it is usually administered by phleboclysis. Using sodium lactate instead of sodium acetate as the buffer for peritoneum dialyszte can reduce the excitation for peritoneum, it can also reduce the influence for depression of cardiac muscle and the resistance of

the around blood vessel.

Dosage and administration

By phleboclysis. The general dose for the adult is 500-1000ml/time, but the dose can be reduced or increased according to the avoirdupois and the age. The speed of administration is 300~500ml/hour.

Attention

Use cautiously if any of the following cases happen:

(1) If the patients with the diabetic is taking caplendus biguanides (especially phenformin), it may inhibit the absorbance of lactic acid of liver, and lactic acid intoxication may happen. (2) The patient with edema companied with Sodium retention trend. (3) Blood pressure may arise for the patients with hypertension. (4) Cardiac insufficiency. (5) The degradation speed of lactate step down for the patients with hepatic inadequacy, it may delay the speed of correcting acidosis. (6) Hypoxia and shock, not enough tissue blood-supply, the metabolism of lactate is slow, it may be influential for the speed to correct acidosis. (7) With excessive drinking, Salicylism toxicosis, Ⅰtype glycogen deposition, lactic acidosis may happen. The product is not appropriate to correct the balance of acid and alkali. (8) With diabetes mellitus ketosis, Acetyl acetic acid, β-hydroxybutyric acid and lactic acid all arise, and may accompany with circulation not good and organ blood-supply not enough, the degradation speed of lactic acid reduce. (9) The patients with renal inadequacy may accompany with water and sodium retention, it may raise the load of heart and blood vessel.

The product is forbidden to use for the following cases: (1) Heart failure and acute pulmonary edema. (2) Cerebral edema. (3) Lactic acidosis is obvious. (4) Severe hepatic inadequacy. (5) Serious renal failure with oliguria or anuria.

The following items should be examined before use: (1) Blood pH or carbon dioxide combining power. (2) The concentration of sodium, potassium, and calcium in the serum. (3) Check the renal function. (4) Blood pressure. (5) Cardiorespiratory function state such as edema, breath lessness, cyanosis, bellows rales, jugular engorge, liver-jugular regurgitation and so on. If necessarily, examine the venous pressure or central venous pressure. (6) When the product is administered for the patients with hepatic inadequacy, make careful inspection momentarily.

Pregnancy and lactation

The administration may intensify edema or raise the blood pressure for the gravida have pregnancy toxinosis.

Substance interactions

When administered with other medicine (such as macrolide antibiotic, alkaloid, sulfanilamide group), pay attention to the incompatibility may happen because of pH value and ionic strength change. Because the product contain Ca+, precipitation may happen when mixed with the blood contain natrium citricum.

Overdose

Overdose may lead to edema or lose balance of ion in body.

Specifications 500ml

Storage

Store below 25℃. Protect from sunlight. Keep out of reach of children

Packaging 500mL Polypropylene bottle

Label

Attached.

Package leaflet

Attached.

Marketing authorisation holder

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