Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product

Sodium Lactate Ringers Injection, 500ml

2. Qualitative and quantitative composition

Each 500ml contains:

Sodium Lactate.....1.55 g

Sodium Chloride.....3.00 g

Potassium Chloride.....0.15 g

Calcium Chloride Dihydrate.....0.10 g.

For full list of excipients, see section 6.1

3. Pharmaceutical form

Solution for Infusion

4. Clinical particulars

4.1 Therapeutic indications

Sodium Lactate Ringers Injection is indicated to adjust the equilibrium of humour electrolyte acid and alkali, Used for metabolic acid toxicosis or dehydration caused by metabolic acid toxicosis.

4.2 Posology and method of administration

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 300~500 ml/hour

4.3 Contraindications

Solutions containing lactate are not for use in the treatment of lactic acidosis.

4.4 Special warnings and precautions for use

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, (Beta) -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 , you should make careful inspection momentarily.

This product osmotic pressure molar concentration is 240-270 mOsmol/kg.

4.5 Interaction with other medicinal products and other forms of interaction

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. The product contains Ca+, precipitation may happen when mixed with the blood contain natrium citricum.

4.6 Fertility, Pregnancy and lactation

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

4.7 Effects on ability to drive and use machine

No studies have been performed on the effects of sodium chloride on the ability to drive or use machines.

4.8 Undesirable effects

(1) For the patients with hepo-calcium (such as uraemia), after correcting acid toxicosis the following cases may happen: limb tingling, ache, twitch, dyspnea and so on. The cause is the reduction of concentration of blood serum calcium

ion. (2) Cardioacceleration, chest distress, breath lessness, pulmonary edema, heart failure and etc. (3) Blood pressure arise. (4) Body weight arise, edema. (5) Over dose may lead to alkali poisoning. (6) The potassium's concentration decline, sometimes hepopotassaemia may happen.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org.

4.9 Overdose

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

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: " Electrolytes", ATC code: "B05BB01"

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 are liver and kidney. When the metabolism of lactic acid is abnormal or out of gear, the curative effect is not very good.

5.2 Pharmacokinetic Properties

The 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.

5.3 Preclinical safety Data

Preclinical safety data of Compound Sodium Lactate Solution in animals are not relevant since its constituents are physiological components in animal and human plasma.

Toxic effects are not to be expected under the condition of clinical application.

The safety of potential additives should be considered separately

6. Pharmaceutical Particulars

6.1 List of excipients

Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this solution must not be mixed with other medicinal products.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Preserved in well closed containers.

6.5 Nature and contents of container

The bags are composed of 500ml polypropylene (PP) bottles. The bags are over wrapped with a protective plastic pouch composed of polypropylene.

The bag size is 500 ml.

Outer carton contents: 30 bottles of 500 ml.

6.6 Special precautions for disposal and other handling

No special requirements

7.0 Marketing Authorization Holder
NANJING SINO PHARMACEUTICAL LTD

8. Marketing Authorization Number
H2025/CTD11062/24488
9. Date of first authorization/renewal of the authorization
8/10/2025
10. Date of revision of the text
8/10/2025