SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 name of the medicinal product

Trade name: Compound sodium lactate intravenous infusion BP

International non-proprietary name *(INN):*
Sodium Lactate as Lactate
Sodium Chloride
Potassium Chloride
Calcium Chloride Dihydrate

1.2 Strength

Each 100 ml of the infusion contains:
Sodium lactate as lactate: 0.32g
Sodium chloride: 0.6g
Potassium chloride: 0.04g
Calcium chloride Dihydrate: 0.027g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Component	QUANTITY GMS/500MLS
Sodium lactate as lactate	1.6
Sodium chloride	3.0
Potassium chloride	0.2
Calcium chloride Dihydrate	0.135
Water for injection	QS
Hydrochloric Acid	$15x10^{-4}$ ml

3. PHARMACEUTICAL FORM

Solution infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is intended for restoring the electrolyte balance and water for hydration. A combination of multiple electrolytes and sodium lactate, alkalinising agent, will provide electrolyte balance and normalise the pH of the acid-base balance of the physiological system

4.2 Posology and method of administration

Compound Sodium Lactate Intravenous Infusion BP is administered by a doctor or a nurse. The doctor will decide on how much to administer and when it is to be given. This will depend on the patient's age, weight, condition, the reason for treatment and whether or not the infusion is being used to deliver or dilute another medicine. Compound Sodium Lactate Intravenous Infusion BP will usually be administered through a plastic tube attached to a needle in a vein. The amount administered may also be affected by other treatments the patient is receiving. Compound Sodium Lactate Intravenous Infusion BP should NOT be administered after the expiry date, which is stated on the container label. The expiry date refers to the last day of the month. Compound Sodium Lactate Intravenous Infusion BP must not be administered if there are particles floating in the solution or if the pack is damaged in any way. Any unused solution should be thrown away. Compound Sodium Lactate Intravenous Infusion BP must NOT be administered from a bottle that has been partly used.

4.3 Contraindications.

DO NOT administer Compound Sodium Lactate Intravenous In-fusion BP if the patient is suffering from any of the following conditions:• Known hypersensitivity to sodium lactate• Congestive heart failure or severe impairment of renal function• Clinical states in which the administration of sodium and chloride is detrimental• In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, through the same infusion line. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid. If another medicine is to be added to the solution for infusion always read the patient information leaflet of that medicine. This way you can check to see if that medicine is safe to be administered with the infusion to the patient.

4.4 Special warnings and precaution for use

Do not use if the container is found leaking upon squeezing, if the solution is not clear or if the solution contains particulate matter.

Please verify if the patient has had any of the following medical conditions:

• Heart failure
• Respiratory failure (lung disease)
• Poor kidney function
• Reduced production of urine (oliguria or anuria)
• Excess water in the body (water intoxication)
• Head injury within 24 hours
• A high pressure within the skull (intracranial hypertension) • A stroke due to a clot in a blood vessel in the brain (ischemic stroke)

When this infusion is administered, the patient's blood and urine samples must be taken to monitor:

• The amount of chemicals such as potassium in their blood (plasma electrolytes)
• The amount of Compound Sodium Lactate Compound Sodium Lactate Intravenous Infusion BP must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together.

4.5 Interactions with other medicinal products and other forms of interaction

Compound Sodium Lactate Intravenous Infusion BP and other medicines taken at the same time can affect each other

4.6 Pregnancy and lactation

Verify if the patient is pregnant or breast feeding. Compound Sodium Lactate Intravenous Infusion BP can be used safely during pregnancy, giving birth (labour) or breastfeeding. However, if another medicine is to be added to the solution for infusion during pregnancy or breast-feeding:

• Read the patient information leaflet of the medicine that is to be added.

Use in Children

The potential risks and benefits for each specific patient should be carefully considered before using for pediatric use. Safety and effectiveness in paediatric patients have not been established by adequate and well controlled trials, however, the use of electrolyte solutions in the paediatric population is referenced in the medical literature. Do Not administer Compound Sodium Lactate Intravenous Infusion BP to babies less than 28 days, with concomitant administration of Ceftriaxone (even in separate infusion lines), due to fatal Ceftriaxone-Calcium salt precipitation.

4.7 Effects on ability to drive and use machines

This product does not affect ability to drive and use machines.

4.8 Undesirable effects

Infusion of excess volume may overload the circulation and precipitate heart failure (increased breathlessness, wheezing and distended neck veins). Volume overload is unlikely if the patient is correctly assessed initially and it is unlikely indeed if the patient response is assessed after initial 250ml of infusion. If there is evidence of this complication, the patient should be transported immediately to the nearest suitable referral hospital while receiving high flow Oxygen. Do not give further fluid. Some swelling of hands, ankles and feet may be experienced due to fluid retention in the body. In rare circumstances this may involve the lungs which may cause some breathing difficulties.

4.9 Overdose.

Overdose may lead to oedema or loss of balance of ions in the body. Excess administration of sodium lactate may lead to metabolic alkalosis accompanied by hypokalaemia. When assessing overdose, any additive in this product must also be considered. The effects of overdose may require immediate medical attention and treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In the natural case blood contains a little lactic acid; it is mainly produced by dextrose or hepatin through zymohydrolysis happening in muscles, skin, brain and cells. After the production of lactate, lactic acid will be translated to hepatin or pyruvic acid or come into tricarboxylic acid

circle, be decomposed to water and carbon dioxide. So the last metabolize production is sodium bicarbonate. It can correct metabolizable acid toxicosis. When this 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 the liver and kidney. When the metabolization of lactic acid is abnormal or out of gear, the curative effect is not very good.

- **Pharmacotherapeutic group**: Multiple electrolyte for intravenous infusion
- **ATC CODE:** B05BB01.

5.2 Pharmacokinetic properties

PH of compound sodium lactate is 5.0 – 7.0; it can be absorbed quickly after orally, and can be oxidized by the liver within 1-2 hours, with the metabolite products sodium bicarbonate. But it is usually administered by phleboclysis. Using sodium lactate instead of sodium acetate as the buffer for peritoneum dialysate can reduce the excitation for peritoneum; it can also reduce the influence for depression of cardiac muscle.

5.3 preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 list of excipients

- Hydrochloric Acid

6.2 incompatibilities

Compatibilities should be checked when additives are used, as additives may Be incompatible. As with all parenteral solutions, before adding medications, Compatibility of the additives with the container must be assessed. It is the responsibility of the administrator to judge the incompatibility of the additive with compound lactate by checking eventual colour change, precipitate, insoluble complexes or Crystals. Before introducing any additive verify its solubility in water at pH of Compound sodium lactate I.V. Infusion solution. When compatible additive is added to this formulation, the solution must be administered immediately, unless dilution has Taken place in controlled and validated aseptic conditions.

6.3 shelf-life

24 months

6.4 Special precautions for storage

Keep this medicine out of sight and reach of children.
Store below 30°C.

6.5 Nature and contents of container

What material is the container of the fluid made of?

The container is made from pharmaceutical grade Low Density Polyethylene complying with Pharmacopoeia requirements of plastics for packaging of preparations for parenteral use. The inert material offers drug compatibility. As the container material does not contain any additives there is no leaching of any substance into the drug solution.

Is the fluid container collapsible?
Yes, the fluid container is self-collapsible. A closed drug delivery system is achieved as the container design allows for easy fluid flow dynamics thus avoiding the risky unconventional local /regional practice of providing a flow vent in a non-collapsible container with a needle pierced through the container wall in a risky hospital environment prone to infectious disease carriers.

What container closure system is provided?
The bottle is closed system container. This system provides two injection ports and resealing ports for the infusion giving set thus giving a high level of drug delivery and administration practice.

6.6 special precautions for disposal
For single use only. Administer immediately following the insertion of a sterile infusion set using aseptic technique. Prime the equipment with the solution to prevent air from entering the system. When additive is used, verify the isotonicity prior to intravenous infusion. In case of adverse reaction, the infusion must be stopped immediately. Discard the unused contents and bottles in which contents have been used. Do not drain the contents in the sinks or water system.

7. REGISTRANT

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L.R. No. 18474/84, Athi River
P.O. Box 51200-00100Nairobi, Kenya

8. 1 MANUFACTURER

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8.2 MARKETING AUTHORIZATION HOLDER.

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9. Date of revision of the text

April 2019

10. Dosimetry – Not applicable

11. Instructions for preparation of radiopharmaceuticals. Not applicable

Product registration No. in Kenya: H2014/CTD1375/014