# SUMMARY OF PRODUCT CHARACTERISTICS

**Compound Sodium Lactate Intravenous Infusion BP (Ringer's Lactate Solution)**

## 1. NAME OF THE MEDICINAL PRODUCT

Compound Sodium Lactate Intravenous Infusion BP (RL) — Ringer's Lactate Solution for Intravenous Infusion

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL of solution contains:

| Active Ingredient | Amount per 100 mL |
|---|---|
| Sodium chloride BP | 0.600 g |
| Calcium chloride BP | 0.027 g |
| Potassium chloride BP | 0.040 g |
| Sodium lactate BP (equivalent to sodium lactate) | 0.320 g |
| Water for injections BP | q.s. to 100 mL |

This provides the following approximate ionic concentrations: $Na^+$ 131 mmol/L, $K^+$ 5 mmol/L, $Ca^{2+}$ 2 mmol/L, $Cl^-$ 111 mmol/L, Lactate 29 mmol/L. Approximate osmolarity 278 mOsm/L; pH 6.0–7.5.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Solution for intravenous infusion.

A clear, colourless, isotonic sterile solution.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Compound Sodium Lactate Infusion BP is indicated for: restoration and maintenance of fluid and electrolyte balance in conditions associated with hypovolaemia, dehydration and electrolyte depletion; as a rehydration fluid and maintenance solution in surgical and trauma patients; isotonic volume replacement in haemorrhage, shock, burns and head injuries; as a vehicle for the intravenous administration of compatible medicinal products. ATC code: B05BB01.

### 4.2 Posology and method of administration

**Adults**

The dose depends on the patient's age, body weight, clinical and biological condition, and the type and severity of fluid and electrolyte imbalance. The infusion rate and volume should be determined by the prescribing physician based on the clinical situation.

Typical starting dose: 500 mL initially, followed by further infusions as clinically required. Usual range: 500 mL–2,000 mL per day depending on clinical needs. Maximum dose: determined by clinical status and haemodynamic monitoring. In burns (Parkland formula): 3–4 mL/kg/per cent burn surface area in the first 24 hours (half in the first 8 hours after injury). In head injury (adults): approximately 2,400 mL/m².

**Paediatric population**

Children (2–11 years): 20 mL/kg over the first hour, then titrated to clinical response. Infants and toddlers (28 days–23 months): adjust dose and rate carefully. In children with burns: 3.4 mL/kg/per cent burn at 24 h and 6.3 mL/kg/per cent burn at 48 h. In severely head-injured children: approximately 2,850 mL/m².

**Elderly**

Consider greater frequency of cardiac, renal and hepatic dysfunction when selecting volume and rate of infusion.

**Method of administration**

For intravenous administration only, through a sterile, non-pyrogenic administration set using aseptic technique. The equipment should be primed with the solution to prevent air entering the system. Do not connect

flexible plastic containers in series. Do not use pressurised venting. Do not administer unless solution is clear and the container is intact. Administer immediately following insertion of infusion set.

### 4.3 Contraindications

- Hypersensitivity to sodium lactate.
- Extracellular hyperhydration or hypervolaemia.
- Severe renal insufficiency with oliguria/anuria.
- Uncompensated cardiac failure.
- Hyperkalaemia.
- Hypercalcaemia.
- Metabolic alkalosis.
- Ascitic cirrhosis.
- Severe metabolic acidosis.
- Conditions associated with elevated lactate levels (hyperlactataemia) or impaired lactate utilisation, such as severe hepatic insufficiency or lactic acidosis.
- Concomitant digitalis therapy.
- Concomitant administration with ceftriaxone in neonates ≤28 days of age, even with separate infusion lines (risk of fatal calcium-ceftriaxone precipitation).

### 4.4 Special warnings and precautions for use

**Hypersensitivity reactions**

Hypersensitivity and infusion-related reactions may occur. Monitor patients closely during infusion. Discontinue immediately if signs of a reaction develop.

**Metabolic and electrolyte monitoring**

Monitor fluid balance, electrolytes (sodium, potassium, calcium, bicarbonate) and acid-base status regularly, especially in patients with renal impairment, cardiac disease, liver disease or on diuretics.

**Fluid and electrolyte overload**

Large-volume infusion can lead to fluid overload, hyponatraemia, hyperkalaemia, hypercalcaemia and metabolic alkalosis. Careful monitoring is required.

**Lactate metabolism**

Lactate is normally converted to bicarbonate in the liver. In patients with impaired lactate utilisation (severe liver disease, lactic acidosis, sepsis), this infusion should be avoided or used with extreme caution.

**Additives**

When additives are incorporated, their compatibility with Compound Sodium Lactate Infusion must be verified, and aseptic technique must be used. Mix thoroughly. Do not store solutions containing additives.

**Air embolism**

Do not connect containers in series to avoid risk of air embolism. Vented IV sets with open vents should not be used with flexible plastic containers.

### 4.5 Interaction with other medicinal products and other forms of interaction

Calcium-containing solutions: Do not administer simultaneously with ceftriaxone via the same infusion line (see section 4.3). Digitalis glycosides: Increased risk of toxicity with hypokalaemia; this infusion is contraindicated with concurrent digitalis therapy. Corticosteroids and ACTH: May increase fluid retention. Antihypertensives: May modify haemodynamic effects. Blood products: Compound Sodium Lactate Infusion should not be used as a vehicle for blood products due to risk of clotting (the calcium content can chelate citrate anticoagulant).

### 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Compound Sodium Lactate Infusion may be used during pregnancy when indicated and with appropriate monitoring.

**Breast-feeding**

No restrictions on use during breast-feeding when clinically indicated.

**Fertility**

No relevant data.

### 4.7 Effects on ability to drive and use machines

Not applicable; this product is administered in a clinical setting.

### 4.8 Undesirable effects

Adverse reactions may result from the volume of infusion or from the electrolyte composition. Fluid overload can cause pulmonary oedema, peripheral oedema and hypertension. Electrolyte disturbances (hyperkalaemia, hypercalcaemia, alkalosis) may occur with large volumes. Hypersensitivity reactions have been reported rarely. Injection site reactions including pain and inflammation may occur.

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

### 4.9 Overdose

Overdosage can result in hypernatraemia, hyperkalaemia, fluid overload, peripheral oedema and pulmonary oedema. Treatment is supportive; discontinue the infusion, monitor and correct electrolyte imbalances. Diuretics or dialysis may be considered in severe cases.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolyte solutions. ATC code: B05BB01.

Compound Sodium Lactate Infusion BP (Ringer's Lactate) is a balanced crystalloid intravenous fluid that closely approximates the composition of extracellular fluid. It restores circulating volume, corrects extracellular fluid depletion and provides a source of physiological electrolytes. Lactate, once metabolised by the liver to bicarbonate, buffers acidosis. The calcium content supports normal neuromuscular function. Potassium corrects hypokalaemia at physiological concentrations.

### 5.2 Pharmacokinetic properties

Following intravenous infusion, the electrolytes distribute into the extracellular fluid compartment (approximately 15 L). Sodium and chloride are excreted primarily via the kidneys. Potassium is regulated by the kidneys with renal tubular secretion. Calcium is distributed into bone, plasma and intracellular compartments. Lactate is metabolised in the liver to bicarbonate with a half-life of approximately 3 hours in normal subjects.

### 5.3 Preclinical safety data

Individual electrolytes are normal body constituents; no preclinical studies are required or relevant for this product class.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Water for injections BP.

### 6.2 Incompatibilities

Compound Sodium Lactate Infusion BP should not be mixed with blood or blood products. Incompatibility with ceftriaxone (see section 4.3 and 4.5). Compatibility with other medicinal products must be verified before admixture.

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

### 6.5 Nature and contents of container

500 mL flexible LDPE plastic containers manufactured by Flexible Form Fill Seal (FFS) technology, with polyolefin inner bag maintaining sterility. Each container is enclosed in an outer overwrap.

### 6.6 Special precautions for disposal and other handling

Remove container from overwrap immediately before use. Inspect visually for particulate matter and discolouration before use; do not administer if abnormalities are found. Do not use containers that are leaking or damaged. Single-use only; discard unused portion. When adding medicinal products: verify compatibility, maintain aseptic technique, mix thoroughly and do not store resulting mixture. Dispose of any unused product or waste material in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

**GOODMED PHARMACY LIMITED**

P.O. Box 76337-00508, Nairobi, Kenya.

## 8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12320/26236

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

01.04.2026

## 10. DATE OF REVISION OF THE TEXT

01.04.2026