

Lactated Ringer's Solution

Solution for Infusion

Composition

1000 mL of solution contain

| | |
|---|--------|
| Sodium chloride | 6.00 g |
| Sodium lactate solution (50% w/w) (equivalent to sodium lactate, 3.12 g) | 6.24 g |
| Potassium chloride | 0.40 g |
| Calcium chloride dihydrate | 0.27 g |

Electrolyte concentrations:

| | |
|-----------|------------|
| Sodium | 131 mmol/L |
| Potassium | 5.4 mmol/L |
| Calcium | 1.8 mmol/L |
| Chloride | 112 mmol/L |
| Lactate | 28 mmol/L |

Excipients:

Water for injections

Pharmaceutical form

Solution for infusion,
Clear, colourless aqueous solution

| | |
|-------------------------|------------|
| Theoretical osmolality: | 277 mOsm/L |
| pH: | 5.0 – 7.0 |

Pharmacotherapeutic Group:

Solutions affecting the electrolyte balance, electrolytes
ATC-Code: B05B B01

Indications

- Fluid substitution under the conditions of undisturbed acid-base balance or mild acidosis
- Isotonic and hypotonic dehydration
- Short-term intravascular volume replacement
- Vehicle solution for compatible electrolyte concentrates and drugs.

Dosage and method of administration

Dosage

The dosage of the solution depends on the fluid and electrolyte requirements of the patient, his/her age, weight, clinical condition and physiological (acid-base) status.

The recommended dosages are:

Adults and adolescents

Maximum daily dose

Up to 40 mL per kg body weight (BW) per day, corresponding to 5.24 mmol sodium per kg BW per day and max. 0.22 mmol potassium per kg BW per day.

Maximum infusion rate:

The infusion rate should be adjusted according to the patient's clinical condition.

The infusion rate should normally not exceed the following values: 5 mL per kg BW per hour

Paediatric patients

Recommended dosage for infants and children:

20 mL – 100 mL per kg BW per day, corresponding to 2.6 – 13 mmol sodium per kg BW per day and 0.08 – 0.54 mmol potassium per kg BW per day.

Maximum infusion rate

on average 5 mL per kg BW per hour, but the value varies with age:

6 – 8 mL per kg BW per hour for infants¹

4 – 6 mL per kg BW per hour for toddlers¹

2 – 4 mL per kg BW per hour for schoolchildren²

¹ infants and toddlers: age range 28 days to 23 months

² schoolchildren: age range 2 years to 11 years

Elderly patients

Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Patients with burns

In order to calculate fluid requirements of patients with burns according to Parkland the following values may be used as guidance:

Adults

During the first 24 h Lactated Ringer's Solution is administered in an amount of 4 mL/kg BW/% burn.

Children

During the first 24 h Lactated Ringer's Solution is administered in an amount of 3 mL/kg BW/% burn.

The following volume is added as maintenance for children according to their weight:

- for children weighing 0 – 10 kg the amount is 4 mL/kg BW/h;
- for children weighing 10 – 20 kg the amount is 40 mL/h + 2 mL/kg BW/h;
- for children weighing more than 20 kg, the amount is 60 mL/h + 1 mL/kg BW/h.

Use as vehicle solution

If Lactated Ringer's Solution is used as vehicle solution for compatible electrolyte concentrates and medicinal products, the instructions for use relating to the medicinal product to be added must be observed.

Method of administration

Intravenous use

Precautions regarding pressure infusion, see section "Special warnings and precautions for use".

Contraindications

- Impairment of lactate utilisation with hyperlactataemia (see also section "Special warnings and precautions for use")
- Hyperhydration

This solution is not indicated for the treatment of severe metabolic acidosis.

Special warnings and precautions for use

This solution should only be administered with particular caution in the following conditions:

- hypertonic dehydration
- hyperkalaemia
- hypernatraemia
- hyperchloraemia
- hypercalcaemia
- hepatic insufficiency

High volume infusions must only be used under specific monitoring in patients with cardiac, renal or pulmonary failure lung or brain oedema. Lactate utilisation may be impaired in the presence of hypoxia or hepatic insufficiency.

Lactated Ringer's Solution contains an amount of potassium that is similar to that of the physiological concentration of potassium in human blood. Nevertheless it is not suitable for the treatment of patients with severe potassium deficiency.

As the solution contains metabolisable ions (e.g. lactate) it may cause metabolic alkalosis. Therefore the solution has to be administered with caution in patients with metabolic alkalosis.

Solutions containing **sodium chloride** should be administered with caution to patients with

- cardiac insufficiency, peripheral oedema or extracellular hyper hydration,
- hypertension, impaired renal function, present or imminent eclampsia, aldosteronism or other conditions or treatment (e. g. corticoids/steroids) associated with sodium retention (see also section "Interactions with other medicinal products and other forms of interaction").

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2 pages

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Solutions containing **potassium** salts should be administered with caution to patients with cardiac disease, conditions predisposing to hyperkalaemia such as renal or adrenocortical insufficiency, acute dehydration, or extensive tissue destruction as occurs with severe burns.

Because of the presence of **calcium**:

- Care should be taken to prevent extravasation during intravenous infusion.
- The solution should be given cautiously to patients with impaired renal function or diseases associated with elevated vitamin D concentrations such as sarcoidosis. Thus administration of calcium containing solutions should be avoided in patients with nephroliths or with a history of nephroliths.
- In case of concomitant blood transfusion, the solution must not be administered via the same infusion set.

Patients with chronic hyponatraemia:

Too rapid correction of serum sodium levels must be avoided in patients with chronic hyponatraemia as rapid increases of serum sodium levels may in rare cases lead to osmotic adverse effects, e.g. the osmotic demyelination syndrome.

Paediatric patients

The solution should be administered only with special care to newborns younger than 3 months.

Use as vehicle solution

Please note: If this solution is used as vehicle solution the safety information of the additive provided by the respective manufacturer has to be taken into account.

Clinical monitoring should include checks of serum electrolyte levels, acid-base balance and water balance.

Serum lactate should be monitored carefully and if lactate accumulates during infusion, the dosage and infusion rate should be reduced or administration of the solution should eventually be discontinued.

In case of pressure infusion, which may be necessary in vital emergencies, all air must be removed from the plastic container and the infusion set before the solution is administered.

Interactions with other medicinal products and other forms of interaction

Administration of Lactated Ringer's Solution in accordance with the recommended indications and contraindications does not increase the plasma concentrations of the electrolytes contained in it. In case there is a rise of any electrolyte's concentration due to other reasons the following interactions should be considered.

- Related to sodium
Corticoids/steroids and carbenoxolone may be associated with the retention of sodium and water (with oedema and hypertension).
- Related to potassium
Suxamethonium, potassium-sparing diuretics (amilorid, spironolactone, triamteren, alone or in association), ACE inhibitors (e.g. captopril, enalapril), Angiotensin II receptor antagonists (e.g. valsartan, losartan), tacrolimus, cyclosporine may increase the concentration of potassium in the plasma and lead to potentially fatal hyperkalaemia notably in case of renal failure increasing the hyperkalaemic effect.
- Related to calcium
 - *Digitalis glycosides* (cardiac glycosides) may undergo enhancement of their effects during hypercalcaemia and lead to serious or fatal cardiac arrhythmia.
 - Thiazid-diuretics and Vitamin D administered simultaneously with calcium may induce hypercalcaemia.
- If bisphosphonates, fluorides, several fluorochinolones and tetracyclines are administered simultaneously with calcium containing solutions the bioavailability (reduced absorption) of above named medicinal products may be reduced.
- Related to lactate
The administration of **bicarbonate or bicarbonate precursor** like lactate leads to **alkalinisation of the urine** with increased renal clearance of acidic drugs (e.g. salicylic acid). The half life of basic medicinal products – especially sympathomimetics (e.g. ephedrine, pseudoephedrine) and stimulants (e.g. dexamphetaminesulphate, fenfluramine hydrochloride) will be prolonged if lactate containing solutions are administered simultaneously.

Paediatric population

No special features

Fertility, pregnancy and lactation

Pregnancy

There is a limited amount of data (less than 300 pregnancy outcomes) from the use of the components of Lactated Ringer's Solution in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

As all components of Lactated Ringer's Solution are naturally present in the body and their biochemical properties are well known the product can be used as indicated. Nevertheless, caution should be exercised in toxemia of pregnancy.

Breast-feeding

Calcium is excreted in human milk, but at therapeutic doses of Lactated Ringer's Solution no effects on the breastfed newborns/infants are anticipated. Therefore Lactated Ringer's Solution can be used during breast-feeding.

Fertility

No special precautions.

Effects on ability to drive and use machines

This medicinal product has no influence on the ability to drive and use machines.

Undesirable effects

Provided the solution is administered according to the directions given, adverse effects are not to be expected.

Overdose

Symptoms

Overdose may result in hyperhydration with increased skin tension, venous congestion, oedema – possibly also lung or brain oedema –, electrolyte and acid-base imbalances as well as serum hyperosmolarity.

Treatment

Cessation of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.

In severe cases of overdose dialysis may be necessary.

Incompatibilities

Medicinal products containing oxalate, phosphate, or carbonate/bicarbonate may cause precipitation upon mixing with Lactated Ringer's Solution.

No other medicinal product or substance should be added to the fluid unless known to be compatible and dilution took place under aseptic conditions.

Expiry date

The product must not be used beyond the expiry date stated on the labeling.

- *after admixture of additives*

From the microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for storage

The product should not be stored above the temperature stated on the label.

For storage conditions after admixture of additives to medicinal product, see section above.

Availability

500 mL, 1000 mL

DR-XY46100

Special precautions for disposal and other handling

No special requirements for disposal.

Only to be used if solution is clear, colourless and the container and its closure do not show visible signs of damage.

Containers are for single-use. Discard container and any unused content after use.

Do not reconnect partially used containers.

Caution

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

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