Compound Sodium Lactate Intravenous Infusion B.P.
(Hartmann's Solution)

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 osmolarity:	277 mOsm/l
pH:	5.0 – 7.0
Pharmacotherapeutic Group:	Solutions affecting the electrolyte balance, electrolytes
ATC-Code:	B05B B01

Therapeutic 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.

Posology and method of administration

Posology

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

The maximum daily dose depends on the fluid and electrolyte requirement of the patient.
Normal fluid requirements are met with 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.

The prescribing doctor may determine individual adaptation of the dose and infusion rate.

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:

The dose is adjusted according to the individual requirements of fluid and electrolytes. Thus the patient's age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.

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

All adults with burns ≥ 15% TBSA should receive fluid according to the Parkland Formula:

During the first 24 h Compound Sodium Lactate is administered in an amount of 4 ml/kg BW/%burn from the time of injury giving ½ in the 1st 8 hrs & ½ in the 2nd 16 hrs.

Children

All children with Burns ≥ 10% TBSA will receive fluid according to the Parkland Formula:
During the first 24 h Compound sodium lactate is administered in an amount of 4 ml/kg/% burn over 24 hrs from the time of injury given ½ in the 1st 8 hrs & ½ in the 2nd 16 hrs.
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 Compound Sodium Lactate 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
- Circulatory overload
- Congestive heart failure
- Hypertension
- Impaired renal function
- Sever liver damage
- Oedema with sodium retention
- Respiratory alkalosis

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

High volume infusions must only be used under specific monitoring in patients with pulmonary failure, lung or brain oedema.

Lactate utilisation may be impaired in the presence of hypoxia or hepatic insufficiency.

Compound sodium lactate 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 or peripheral oedema,
- present or imminent eclampsia, aldosteronism or other conditions or treatment (e. g. corticoids/steroids) associated with sodium retention (see also section "Interaction with other medicinal products and other forms of interaction").

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Solutions containing potassium salts should be administered with caution to patients with cardiac disease, conditions predisposing to hyperkalaemia such as 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 withdiseases 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 in-fusion 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 demyelinisation 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.

Interaction with other medicinal products and other forms of interaction

Administration of Compound Sodium Lactate 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 fluorchinolones and tetracyclines are administered simultaneously with calcium containing solutions the bioavailablility (reduced absorption) of above named medicinal products may be reduced.
- Related to lactate
  The administration of bicarbonate or bicarbonate precursor like lactate leads to alkalini-sation 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 Compound Sodium Lactate in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.
As all components of Compound Sodium Lactate are naturally present in the body and their bio-chemical properties are well known the product can be used as indicated.Nevertheless, caution should be exercised in toxaemia of pregnancy.

Breast-feeding
Calcium is excreted in human milk, but at therapeutic doses of Compound Sodium Lactate no effects on the breastfed newborns/infants are anticipated. Therefore Compound Sodium Lactate 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

Incompatibility has been reported with novobiocin sodium, oxytetracycline hydrochloride, sodium bicarbonate, sodium calcium edetate, and sulphadiazine sodium.

Medicinal products containing oxalate, phosphate, or carbonate/bicarbonate may cause precipitation upon mixing with Compound Sodium Lactate.

No other medicinal product or substance should be added to the fluid unless known to be compatible.

Shelf life

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

- 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.

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.

Presentation

500 ml, 1000 ml

Special precautions for disposal

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.

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Manufactured by:
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