PATIENT INFORMATION LEAFLET
(PIL)

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
HABSON RL (Compound Sodium Lactate Intravenous Infusion BP)

Strength:
Each 100 ml contains:
Sodium Lactate Solution BP
Eq. to Sodium Lactate……0.32% w/v
Sodium Chloride BP……...0.60% w/v
Potassium Chloride BP……...0.04% w/v
Calcium Chloride Dihydrate BP…….0.027% w/v
Water for Injections BP……q.s.

Pharmaceutical form: Solution for Intravenous Infusion
Active Pharmaceutical Ingredient: Sodium Lactate BP, Sodium Chloride BP, Potassium Chloride BP, Calcium Chloride Dihydrate BP

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP IS AND WHAT IT IS USED FOR

Compound Sodium Lactate solution is used in the following indications:
• Restoration of extracellular fluid and electrolytes balances or replacement of extracellular fluid loss where isotonic concentrations of electrolytes are sufficient
• Short term volume replacement (alone or in association with colloid) in case of hypovolaemia or hypotension.
• Regulation or maintenance of metabolic acidosis balance and/or treatment of mild to moderate metabolic acidosis (except lactic acidosis)

2. BEFORE YOU ARE GIVEN COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP Do not use

if you are
• A known 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 increased lactate levels (hyperlactataemia) including lactic acidosis, or impaired lactate utilization, such as severe hepatic insufficiency.
• Concomitant digitalis therapy

Warnings and precautions:

Before you use Compound Sodium Lactate Intravenous Infusion BP

Hypersensitivity reactions

The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop.

Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Ceftriaxone

In patients older than 28 days (including adults), ceftriaxone must not be administered simultaneously with intravenous calcium-containing solutions, including Compound Sodium Lactate solution, 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.

Electrolyte balance

Hypernatraemia

Compound Sodium Lactate solution should only be administered to patients with hypernatraemia after careful consideration of the underlying cause and alternative intravenous fluids. Monitoring of plasma sodium and volume status during treatment is recommended.

Compound Sodium Lactate solution should be administered with particular caution in patients with conditions predisposing to hypernatraemia (such as adrenocortical insufficiency, diabetes insipidus or extensive tissue injury) and in patients with cardiac disease.

Hyperchloraemia

Compound Sodium Lactate solution should only be administered to patients with hyperchloraemia after careful consideration of the underlying cause and alternative intravenous fluids. Monitoring of plasma chloride and acid-base balance during treatment is recommended.

Compound Sodium Lactate solution should be administered with particular caution to patients with conditions predisposing to hyperchloraemia (such as renal failure and renal tubular acidosis, diabetes insipidus), and patients with urinary diversion or patients taking certain diuretics (carbonic anhydrase inhibitors eg acetazolamide) or steroids (androgens, estrogens corticosteroids) and in patients with severe dehydration.

Fluid balance/renal function

Risk of Fluid and/or Solute Overload and Electrolyte Disturbances

Depending on the volume and rate of infusion, intravenous administration of Compound Sodium Lactate solution can cause

• fluid and/or solute overload resulting in overhydration and, for example, congested states, including pulmonary congestion and oedema.
• clinically relevant electrolyte disturbances and acid-base imbalance.

Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.

Taking or using other medicines:
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
Compound Sodium Lactate solution can be used safely during pregnancy and lactation as long as the electrolyte- and fluid balance is controlled.
It is reminded that calcium crosses the placenta and is distributed into breast milk.
Compound Sodium Lactate solution should be administrated with special caution for pregnant women during labour particularly as to serum-sodium if administered in combination with oxytocin.
When a medication is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.

Driving and using machines
There is no information of the effects of Compound Sodium Lactate solution on the ability to operate an automobile or other heavy machinery.

3. HOW TO USE COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP

Adults, older people and children:
Fluid balance, serum electrolytes and acid-base balance should be monitored before and during administration, with particular attention to serum sodium in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Monitoring of serum sodium is particularly important for hypotonic fluids.
Compound Sodium Lactate solution has a tonicity of 278 mOsm/l (approx.)
The infusion rate and volume depend on the age, weight, clinical condition (e.g. burns, surgery, head-injury, infections), and concomitant therapy should be determined by the consulting physician experienced in intravenous fluid therapy.
Recommended dosage:
The amount of Compound Sodium Lactate solution needed to restore normal blood volume is 3 to 5 times the volume of lost blood.
The recommended dosage is:

- for adults: 500 ml to 3 L/24h
- for infants, toddlers and children: 20 ml to 100 ml/kg/24 h

Administration rate:
The infusion rate is usually 40 mL/kg/24h in adults.
Use in paediatric patients
The safety and efficacy of Compound Sodium Lactate solution in children has 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. Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.
Paediatric infusion rates is 5 ml/kg/h in average but the value varies with age:

- infants: 6-8 mL/kg/h,
- toddlers: 4-6 mL/kg/h
- children: 2-4 mL/kg/h .

In children with burns, the dose is on average 3.4 mL/kg/per cent burn at 24 h post-burn and 6.3 mL/kg/per cent burn at 48 h.
In severely head-injured children the dose is on average 2850 mL/m2.
Infusion rate and total volume can be higher in surgery or in case of need.

Method of administration:
The solution is for intravenous administration through a sterile and non-pyrogenic administration set using aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.
The solution should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear, free from visible particles and the seal is intact. Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set.
Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.
Additives may be introduced before infusion or during infusion through the injection site. When making additions to Compound Sodium Lactate solution, aseptic technique must be used. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following section contains the most serious side effects that you can recognise yourself:

Immune System Disorders
Hypersensitivity/Infusion reactions including
Anaphylactic/Anaphylactoid reaction, possibly manifested by
one or more of the following symptoms: Angioedema, Chest
pain, Chest discomfort, Decreased heart rate, Tachycardia, Blood pressure decreased, Respiratory distress, Bronchospasm, Dyspnea, Cough, Urticaria, Rash, Pruritus,
Erythema, Flushing, Throat irritation, Paresthesias, Hypoesthesia oral, Dysgeusia, Nausea, Anxiety, Pyrexia,
Headache

Metabolism and nutrition disorders
Hyperkalaemia
Hospital acquired hyponatraemia*
Nervous system disorders
Acute hyponatraemic encephalopathy*
General Disorders and Administration Site Conditions
Infusion Site Reactions manifested by one or more of the following symptoms: Phlebitis, Infusion site inflammation, Infusion site swelling, Infusion site rash, Infusion site pruritus, Infusion site erythema, Infusion site pain, Infusion site
burning

5. HOW TO STORE COMPOUND SODIUM LACTATE INTRAVENOUS INFUSION BP

Store below 30°C. Protect from light. Do not refrigerate or freeze.

6. FURTHER INFORMATION

What Compound Sodium Lactate Intravenous Infusion BP contains
Active ingredient is Sodium Lactate Solution BP eq. to Sodium Lactate ,Sodium Chloride Potassium Chloride, Calcium Chloride. Also contains Water for Injections BP,

Hydrochloric acid BP, Sodium Hydroxide BP

What Compound Sodium Lactate Intravenous Infusion BP looks like and contents of the pack

1x500ml LDPE Bottle, with pre-printed label, with helmet cap/euro head cap, wrapped in a BOPP film.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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