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Directions for Use

B. Braun Melsungen AG · Carl-Braun-Straße 1, 34212 Melsungen, Germany

B. Braun Compound Sodium Lactate Intravenous Infusion B.P.

(Hartmann's Solution)

Composition
1000 ml of solution contain

Active substances:

Sodium Chloride	6.00 g
Sodium Lactate	3.12 g
Potassium Chloride	0.40 g
Calcium Chloride Dihydrate	0.27 g

Excipients:
Water for Injections

Theoretical osmolarity:	277 mOsm/l
Titration acidity:	< 1 mmol/l
pH:	5.0 - 7.0

Electrolyte concentrations:

Sodium	131 mmol/l
Potassium	5.4 mmol/l
Calcium	1.8 mmol/l
Chloride	112 mmol/l
Lactate	28 mmol/l

Pharmaceutical form
Solution for infusion

Pharmaco-therapeutic group
Solution for fluid and electrolyte supply.

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

Contraindications
B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) must not be administered to patients in states of hyperhydration.

Special warnings and precautions for use
B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) should only be administered with particular caution in the presence of the following conditions:
- Hypertonic dehydration,
- Hyperkalaemia
- Hypernatraemia,
- Hyperchloraemia,
- Renal insufficiency with tendency to hyperkalaemia,
- Disorders necessitating restriction of sodium intake, such as cardiac insufficiency, generalised oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency

Clincal monitoring should include regular checks of the serum ionogram and the water balance.
In case of pressure infusion, which may be necessary in vital emergencies, all air must be removed from the container and the infusion set before the solution is administered.

Interactions
Drugs containing oxalate, phosphate, or carbonate/ bicarbonate may cause precipitation upon mixing with B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution).

Dosage
The dosage of B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) depends on age, weight and clinical condition of the patient

Maximum daily dose:
40 ml per kg body weight per day.

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 body weight per hour, corresponding to 1.7 drops per kg body weight per min.
If B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) is used as vehicle solution, the instructions for use relating to the medicament to be added should be observed.

Children and the elderly
According to individual requirements.
Precautions re. pressure infusion, see section "Precautions for Use" and figures at the end of this leaflet.

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.

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

Undesirable effects
Hyperchloraemia may occur during administration.

Note
Patients are advised to inform their doctor or pharmacist if they notice any adverse effect in connection with the admnistration of this medicine.

Pharmacodynamics
B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) has a similar electrolyte composition as the extracellular fluid, with a total cation content of 138 mmol/l. It is used for correction of serum electrolyte and acid-base imbalances. Electrolytes are administered in order to achieve or to maintain a normal osmotic situation in both the extra- and the intracellular space.
Lactate is oxidised and exerts a mild alkalinising effect. On account of the proportion of matabolised anions B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) is particularly indicated in patients with a tendency to acidosis.

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Pharmacokinetics
Administration of B. Braun Compound Sodium Lactate Intravenous Infusion B.P. (Hartmann's Solution) directly results in replenishment of the interstitial space which amounts to about 2/3 of the extracellular space. Only 1/3 of the administered volume stays in the intravascular space. Thus the solution has a short haemodynamic effect.

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

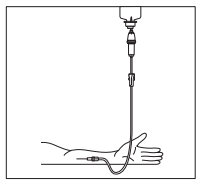
Instructions for storage / use / handling
Only to be used if solution is clear and the container undamaged.
Do not store above 30 °C.

Date of last revision: 12.2018

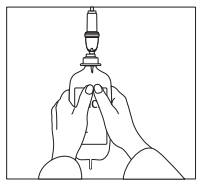
General guidelines on fluid and electrolyte intake:
A level of 30 ml of the solution per kg body weight per day only covers the physiological basic fluid requirements. Post-operatively and in intensive care patients there is an increased requirement for fluid intake on account of the limited concentrating capacity of the kidneys and the increased excretion of metabolites, so that it is necessary to increase the fluid intake to about 40 ml/kg body weight per day. Additional losses (e.g. fever, diarrhoea, fistulae, vomiting etc.) must be compensated for by a still higher, individually adapted fluid intake. The actual and individual fluid requirement is determined by the stepwise monitoring necessary in every case (e.g. urine excretion, osmolarity in serum and urine, determination of substances excreted).
The basic substitution of the most important cations sodium and potassium amounts to approx. 1.5 – 3 mmol per kg body weight per day and 0.8 – 1.0 mmol per kg body weight per day respectively. The actual requirement during infusion therapy depends on appropriate determinations of the electrolyte balance and on the laboratory monitoring of the plasma concentrations.

Instructions for Handling the Ecoflac plus Container

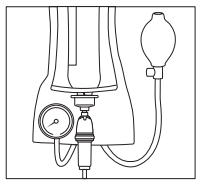
1. Gravity infusion
- Insert infusion set, fill half of drip chamber, fill infusion tube avoiding bubbles.
- Close air vent of infusion set.
- Connect infusion tube to cannula/catheter.
- Open clamp and start infusion with air vent closed



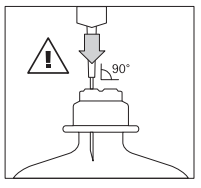
2. Pressure infusion
- Insert infusion set.
- Hold container upright.
- Leave clamp open, expel air from container and fill half of drip chamber.
- Turn container and expel air from infusion device.
- Close clamp.



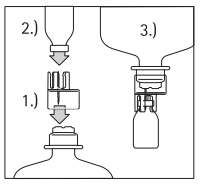
- Place container in pressure cuff.
- Build up pressure.
- Open clamp and start infusion.



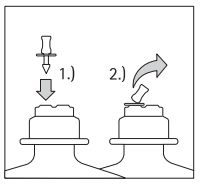
3. Admixture of additives
Addition via cannula
- Insert cannula vertically.



Addition using the transfer cap (Ecoflac® Mix)
1.) Attach transfer cap to the container.
2.) Attach vial to the other end (click!).
3.) Transfer solution into the vial containing the additive by pressing the Ecoflac® plus container. Dissolve additive completely. Turn Ecoflac® plus container with attached vial upside down. Press air into the vial until all solution has been transferred into the Ecoflac® plus container.



Documentation of addition and re-sealing the injection port with Ecopin®
1.) Insert Ecopin® into injection port
2.) Break off handle



Product registration holder:
B. Braun Medical Industries Sdn. Bhd.
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Manufactured by:
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