B|BRAUN

PRODUCT INFORMATION

B. Braun (Aust) Intravenous Replacement Fluids

* **0.9% Sodium Chloride Intravenous Infusion BP**
* **5% Glucose Intravenous Infusion BP**
* **0.9% Sodium Chloride and 5% Glucose Injection BP**
* **Compound Sodium Lactate Injection BP (Hartmann's solution)**

Composition: The solutions have the following formulations (g/L):

	0.9% NaCl	**5% Glucose**	**0.9% NaCl and 5% Glucose**	**Compound Na Lactate**
Sodium chloride	9g	---	9g	6g
Glucose Monohydrate	---	55g (equivalent to anhydrous glucose 50g)	55g (equivalent to anhydrous glucose 50g)	---
Potassium chloride	---	---	---	0.4g
Calcium chloride	---	---	---	0.27g
Sodium lactate (as 50% soln)	---	---	---	3.12g

and have the following content of electrolytes (mmol/L), total osmolality and pH:

	0.9% NaCl	**5% Glucose**	**0.9% NaCl and 5% Glucose**	**Compound Na Lactate**
Sodium	154	---	154	131
Chloride	154	---	154	111
Potassium	---	---	---	5.4
Calcium	---	---	---	1.8
Lactate	---	---	---	29
Total Osmolality	308 mOsm/L	278 mOsm/L	585 mOsm/L	278 mOsm/L
pH	4.5 – 7.0	3.5 - 5.5	3.5 - 5.5	5.0 - 7.0

Solutions containing 5% glucose provide 835kJ/L.

Description: B. Braun intravenous replacement solutions are clear to colourless solutions intended for intravenous infusion.

Pharmacology: B. Braun intravenous replacement solutions provide various electrolytes and/or glucose in sterile solutions intended for intravenous infusion. The solutions are all nominally isotonic, except for the 0.9% sodium chloride and 5% glucose solution which is hypertonic.

Sodium chloride, potassium chloride and calcium chloride are present in the various solutions in concentrations suitable for replacement therapy under different clinical conditions (see indications). Sodium lactate is included as a source of bicarbonate ions following metabolism of lactate ions *in vivo.*

Glucose is a necessary part of intravenous therapy regimes where the supply of energy is a requirement. Glucose is the only natural substrate directly utilised by all body tissues and is essential for energy supply to the brain, peripheral nerves, red blood cells, bone marrow and the renal medulla.

Indications: The solutions are indicated for intravenous fluid therapy designed to correct deficiencies in hydration, electrolyte and energy levels. The solutions may also be used as solvents for intravenously administered drugs where compatibility has been established.

* 0.9% sodium chloride injection may also be used for irrigation of wounds and moistening of wound dressings

* Compound Sodium Lactate Solution is particularly suitable for the replacement of extracellular fluid loss where isotonic dehydration is evident and in burn therapy.

Contraindications: The use of intravenous replacement therapy solutions is contraindicated in patients with hyperhydration or oedema, hypertension and patients whose electrolyte balance has not been fully assessed in order to determine the most suitable fluid for therapy.

Solutions containing sodium lactate are contraindicated in patients with symptoms of alkalosis or renal insufficiency, shock conditions and in patients with severe liver damage who are unable to convert lactate to bicarbonate.

Warnings and Precautions: For paediatric patients requiring electrolyte and fluid replacement dosage should be adjusted accordingly.

Intravenous solutions, particularly if hypertonic, should be used with care under expert supervision in paediatric patients.

The fluid and electrolyte balance of the patients should be monitored during the course of intravenous therapy and, if necessary, adjustments in the dosage regimen made. Particular care should be taken in patients with renal or cardiac impairment and in the elderly.

Glucose solutions may cause or exacerbate hyperglycaemia and glucosuria, and patients should be carefully monitored. Glucose solutions alone should not be used for long term fluid replacement as they do not contain electrolytes. Glucose solutions without electrolytes are usually incompatible with blood products. Infusion of solutions containing glucose in patients with marginal thiamine status may precipitate symptoms of thiamine deficiency.
Hypertonic solutions should be infused slowly to prevent pain and irritation at the injections site. They should preferably given via a large central vein.

Use during Pregnancy and Lactation: There have been no adverse reports following the appropriate use of the intravenous infusion fluids included in this leaflet when used to compensate for electrolyte and fluid losses during pregnancy and lactation. Adequate renal function is essential.

Interactions with other drugs: Increasing the blood and plasma volume by the addition of intravenous fluids may alter the distribution and plasma concentration of other drugs. Monitoring of plasma concentrations of concomitantly administered drugs with narrow therapeutic ranges is recommended. When used as a vehicle for drug delivery, the product information documents of the drug(s) for infusion should be examined to establish compatibility.

Adverse Reactions: Fluid and electrolyte balance should be monitored during therapy to avoid fluid overload and electrolyte disturbances which may result in adverse events. Symptoms of fluid overload such as peripheral oedema and shortness of breath may occur if volumes in excess of an individual patient's needs are infused. Symptoms associated with electrolyte imbalance (including hyponatraemia, hypokalaemia, and hypomagnesaemia) may occur and should be treated by reducing the infusion rate and applying supportive measures.

With glucose solution infusions, hyperglycaemiaa and glycosuria may occur when infusion rates exceed 0.5 g/kg/hr.

Vitamin B-complex deficiency may be associated with intravenous fluid replacement using solutions containing glucose.

Intravenous administration of glucose solutions may cause local pain, vein irritation and thrombophlebitis, and tissue necrosis if extravasation occurs.

For a full description of the symptoms and treatment of overdosage with electrolyte solutions please refer to the Overdosage section.

Due care should be taken with intravenous technique to avoid injection site reactions and infections. If institutional infection control guidelines are in place these should be consulted.

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.

Dosage and Administration:

Dosage should be adjusted according to individual requirements including the age, weight and clinical condition of the patient. Particular care should be taken in the determination of doses and infusion rates for paediatric patients, post-operative patients and patients with burns. Rates of infusion to be instituted will depend on the total fluid, electrolyte or glucose load required, the fluid being infused and the urgency of the situation.

It is recommended that textbooks of medicine, surgery, intensive care and paediatrics be consulted to determine the optimal solution and infusion rate for each patient.

The compatibility of any additives to the solutions should be checked before use.
Solutions containing glucose should not be administered through the same lines as those containing whole blood due to the chance of haemolysis and clumping.

Compatible additives may be injected into the container through the second port. Shake container thoroughly to mix.

For use on a single occasion in a single patient. Contains no antimicrobial preservative.

How to use the Ecoflac Plus Container
1. Remove aluminium strip from twin port cap by gently pulling it backwards.
2. Withdraw protective cover from spike and make sure that the roller clamp on the tubing is closed properly.
3. Insert spike into the container, using either of the two ports available. Compatible additives may be injected into the container through the second port. Shake container thoroughly to mix.
4. Suspend container and fill drip chamber until about half full by simply squeezing lower part of drip chamber several times.
5. Open roller clamp and expel air by running fluid through tubing.
6. Close roller clamp again and perform venipuncture.
7. Connect tubing to vein needle, set the required infusion rate and start infusion.

Containers

The Ecoflac Plus® container has been designed in such a manner that it does not require a giving set with an air-vent. The container empties automatically under atmospheric pressure, except for a small residual portion of fluid at the end of infusion, thus preventing the inadvertent entry of air into the system. To compensate for the intended unused fluid residue the container contains slightly more fluid than the nominal volume declared.

Overdosage: Symptoms of overdosage with intravenous solutions are related to excessive electrolyte levels and fluid imbalance. The following symptoms are indicative of overdosage and indicate the need for immediate measurement of serum electrolyte levels and blood glucose, calculation of fluid balance, ECG monitoring and commencement of appropriate supportive symptomatic treatment:

- shortness of breath, peripheral oedema
- nausea, vomiting and diarrhoea
- abdominal cramps
- listlessness, weakness (general and muscular)
- paraesthesia of the extremities, paralysis
- mental confusion
- cardiac complications

Hyperkalaemia should be treated by eliminating the intake of potassium and potassium sparing diuretics and infusion of 50 - 125g of dextrose over one hour with insulin. Severe cardiac toxicity resulting from hyperkalaemia requires immediate attention and may be treated by intravenous injection over 1-5 minutes of 10 - 20mL Calcium Gluconate Injection 10%.

Severe cases of hypernatremia and hyperkalaemia may benefit from dialysis.

Storage Conditions: The solutions should be stored in a cool, dry place, below 25^0C and used before the expiry date on the container.

Presentation: The solutions are available in LDPE bottles

0.9% Sodium Chloride	50mL,100mL, 250mL, 500mL, 1L
5% Glucose	100mL, 250ml, 500mL, 1L
0.9% Sodium Chloride and 5% Glucose	500mL, 1L
Compound Sodium Lactate (Hartmann's Solution)	500mL, 1L

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