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# AUSTRALIAN PRODUCT INFORMATION

B. Braun Australia Pty Ltd

**B. Braun (Australia) Intravenous Replacement Fluids**

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

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## 1. NAME OF THE MEDICINE

Sodium Chloride, Glucose, Sodium Lactate

## 2. QUALITATIVE AND QUANTITATIVE 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** | --- | 50g | 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.

## 3. PHARMACEUTICAL FORM

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

## 4. CLINICAL PARTICULARS

### 4.1 THERAPEUTIC 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.

### 4.2 DOSE AND METHOD OF 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.

**Method of administration**

Intravenous infusion

**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.

### 4.3 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.

### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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 be preferably given via a large central vein.

**Use in the elderly**

Particular care should be taken in patients with renal or cardiac impairment and in the elderly.

**Paediatric use**

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.

**Effects on laboratory tests**

No data available.

### 4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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.

### 4.6 FERTILITY, PREGNANCY AND LACTATION

**Effects on fertility**

No data available.

**Use in pregnancy**

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.

**Use in 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.

### 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

### 4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

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, hyperglycaemia 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 Overdose 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.

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# CONSUMER MEDICINE INFORMATION

B. Braun Australia Pty Ltd

**B. Braun (Australia) Intravenous Replacement Fluids**

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

*This leaflet provides a summary of some of the important things you need to know about this medicine. Only your doctor and pharmacist are able to weigh up all the relevant facts about the use of this medicine in your condition and you should consult them for further details. More detailed and technical information is available on request from your doctor or pharmacist.*

The solutions described above are clear colourless solutions intended for intravenous infusion. They contain water and various electrolytes i.e. simple chemicals such as sodium, calcium, potassium etc. Some also contain glucose as a source of energy.

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

| | 0.9% NaCl | 5% Glucose | 0.9% NaCl and 5% Glucose | Compound Sodium Lactate |
|---|---|---|---|---|
| **Sodium chloride** | 9g | --- | 9g | 6g |
| **Glucose** | --- | 50g | 50g | --- |
| **Potassium chloride** | --- | --- | --- | 0.4g |
| **Calcium chloride** | --- | --- | --- | 0.27g |
| **Sodium lactate (as 50% soln)** | --- | --- | --- | 3.12g |

Solutions containing 5% glucose provide 835kJ/L.

**What are the products used for?** Electrolyte replacement solutions are used to replace fluid and electrolytes which have been lost from the body due to illness or injury.

**How do they work?** The solution chosen by your doctor is infused slowly into a vein and provides water as well as some or all of the following electrolytes: sodium, chloride, potassium and bicarbonate ions to replace those lost. The solution may also contain glucose.

**Before using this product:** Please note that the solutions should not be used if the container is found to be leaking or the solution is not clear.

* Tell your doctor if you have kidney or liver problems or if you have high levels of potassium in your blood.

**Directions for Use:** This product has been chosen by your doctor and will be given to you as an intravenous drip. The amount of solution and the rate at which it is given will depend on how much fluid replacement is necessary and on your age and weight.

When using the container remove the aluminium strip from the cap and attach tubing by inserting a needle through the port into the bottle. The container has been designed to empty and collapse during use. A small residual volume of solution remains at the end of infusion to prevent accidental entry of air into the tubing. Other medications can be added if necessary, by injecting through the second port and gently shaking the container.

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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.

**Reporting suspected adverse effects**
Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

### 4.9 OVERDOSE
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.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACODYNAMIC PROPERTIES
Mechanism of action
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 sodium chloride/glucose solutions which are 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 the metabolism of lactate ions in vivo.

Glucose is a necessary part of intravenous therapy regimens 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.

**Clinical trials**
No data available.

### 5.2 PHARMACOKINETIC PROPERTIES
No data available.

### 5.3 PRECLINICAL SAFETY DATA

**Genotoxicity**
No data available.

**Carcinogenicity**
No data available.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 LIST OF EXCIPIENTS
Water for injections

### 6.2 INCOMPATIBILITIES
Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

### 6.3 SHELF LIFE
In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging. Shelf Life 3 years.

### 6.4 SPECIAL PRECAUTIONS FOR STORAGE
The solutions should be stored in a cool, dry place, below 25˚C and used before the expiry date on the container.

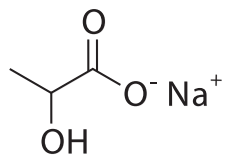
### 6.5 NATURE AND CONTENTS OF CONTAINER
The solutions are available in LDPE bottles.

| | |
|---|---|
| 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 |

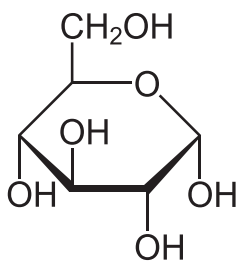
### 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

### 6.7 PHYSICOCHEMICAL PROPERTIES

**Chemical Structure**
Sodium chloride – Na-Cl
Sodium lactate




Glucose




**CAS Number**
Sodium chloride – 7647-14-5
Sodium lactate – 867-56-1
Glucose – 50-99-7

## 7. MEDICINE SCHEDULE (POISONS STANDARD)
S4 (Prescription Only Medicine)

## 8. SPONSOR
B. Braun Australia Pty Ltd
Level 5, 7-9 Irvine Place
Bella Vista
NSW 2153
Australia

Toll free number: 1800 251 705

## 9. DATE OF FIRST APPROVAL
26 May 1994

## 10. DATE OF REVISION
12 August 2022

## SUMMARY TABLE OF CHANGES

| Section Changed | Summary of new information |
|---|---|
| All | Reformatted as per new TGA PI format<br>Changed sponsor address,<br>included Toll Free Number |

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**B. Braun Melsungen AG**
34209 Melsungen, Germany

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**Unwanted Effects:** It is unlikely that side effects occur if the solutions are infused at the correct rate to replace lost fluid, however disturbances in fluid or electrolyte balance in the body may occur (see below at Overdosage for a description of possible side effects).
If any side-effects are noticed or if the site of injection is painful your doctor or nurse should be notified.

**Overdosage:** Overdosage with the solutions may result in symptoms caused by too much fluid or electrolytes. The following symptoms should be immediately reported to your doctor:
- shortness of breath
- puffiness in the hands or ankles
- nausea, vomiting and diarrhoea
- stomach cramps
- listlessness, weakness (general and muscular)
- burning or prickling of the fingers or toes
- mental confusion
- irregular heart beat

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

**Presentations:**

| | | | |
|---|---|---|---|
| 0.9% Sodium Chloride | | Glucose 5% | |
| 50mL | AUST R 154967 | 100mL | AUST R 98318 |
| 100mL | AUST R 98311 | 250mL | AUST R 98343 |
| 250mL | AUST R 98312 | 500mL | AUST R 49331 |
| 500mL | AUST R 49335 | 1000mL | AUST R 49332 |
| 1000mL | AUST R 49337 | | |
| Sodium Chloride 0.9% and Glucose 5% | | Compound Sodium Lactate: | |
| 500mL | AUST R 49333 | 500mL | AUST R 99547 |
| 1000mL | AUST R 49334 | 1000mL | AUST R 49330 |

**For further information:**
*This leaflet provides a summary of some of the important things you need to know about this medicine. Only your doctor and pharmacist are able to weigh up all the relevant facts about the use of this medicine in your condition and you should consult them for further details.*

**Sponsor:** B. Braun Australia Pty Ltd
Level 5, 7-9 Irvine Place
Bella Vista, NSW 2153
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Toll free number: 1800 251 705

This leaflet was prepared in August 2022

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