0005/12632985/0324

Directions for use
Read carefully!

0.9% Sodium Chloride Intravenous Infusion B.P.

(Normal Saline)

Composition

Each 1000 ml contains :	
Sodium Chloride	9.0 g
Water for Injections to	1000 ml
Electrolytes :	mmol/l (mEq/l)
Na^+	154
Cl^-	154
Osmolarity :	308 mOsm/l

Product Description
A clear, colourless aqueous solution.

Pharmacodynamics
Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium and potassium are the major mediators of bioelectric processes within the body.
The sodium content and the liquid metabolism of the body are closely coupled to each other. Each deviation of the plasma sodium concentration from the physiological one simultaneously affects the fluid status of the body.
An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolality.
A 0.9 per cent sodium chloride solution has the same osmolarity as plasma. Administration of this solution primarily leads to a replenishment of the interstitial space which is about 2/3 of the entire extracellular space. Only 1/3 of the administered volume remains in the intravascular space. Therefore the haemodynamic effect of the solution is of short duration only.

Pharmacokinetics
The total sodium content of the body is ca. 80 mmol/kg of which ca. 97 % is extracellular and ca. 3 % intracellular. The daily turnover is ca. 100 - 180 mmol (corresponding to 1.5 - 2.5 mmol/kg body weight).
The kidneys are the major regulator of the sodium and water balances. In cooperation with the hormonal control mechanisms (renin-angiotensin-aldosterone system, antidiuretic hormone) and the hypothetical natriuretic hormone they are primarily responsible for keeping the volume of the extracellular space constant and regulating its fluid composition.
Chloride is exchanged for hydrogen carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance.

Indications
- Fluid and electrolyte substitution in hypochloraemic alkalosis,
- Chloride losses,
- Short-term intravascular volume substitution,
- Hypotonic dehydration or isotonic dehydration,
- Vehicle solution for compatible electrolyte concentrates and medicaments,
- Externally for wound irrigation and for moistening of wound tamponades and dressings.

Dosage

Recommended dosage schedule
The dose is adjusted according to the actual requirements of water and electrolytes:

Maximum daily dose:
40 ml/kg BW, corresponding to 6 mmol of sodium per kg BW

Infusion rate:
Up to 5 ml/kg BW/h, corresponding to 1.7 drops/kg BW/min
The amount of solution to be used for wound irrigation or moistening depends on actual requirements.

Route of administration I.V.

Contraindications
Hyperhydration, hypernatraemia, hypokalaemia, acidotic situations, hypertension

Precautions

Special warnings
0.9 % w/v Sodium Chloride Intravenous Infusion BP should only be administered with caution in cases of
- hypokalaemia
- hypernatraemia
- hyperchloraemia
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency.

Precautions for use
Clinical monitoring should include checks of the serum ionogram, the water balance, and the acid-base status.
High infusion rates should be avoided in cases of hypertonic dehydration because of possible increases of plasma osmolarity and plasma sodium concentration.
* 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 With Other Medicaments
When mixing with other medicaments, physical or chemical incompatibilities should be considered.

Side effects/Adverse reactions
Inappropriate and excessive use of Sodium Chloride Infusions may lead to hypernatraemia. This may occur as a result of existing renal function impairment, aldosteronism, brain injury or glucose overloading in parenteral feeding.

Symptoms and treatment for overdosage

Symptoms
Overdose may result in hypernatraemia, hyperchloraemia, overhydration, hyperosmolarity of the serum, and metabolic acidosis.

Emergency treatment, antidotes
Immediate cessation of administration, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.
In such an event, the use of sodium-containing infusions should be ceased, and other sodium intake controlled.
Very occasionally in severe hypernatraemia, dialysis may be indicated.

Usage during pregnancy
0.9% Sodium Chloride Intravenous Infusion can be used as indicated.

Shelf life
The product must not be used beyond the expiry date stated on the label.

Storage
The product should not be stored above the temperature stated on the label.

Presentation
50 ml, 100 ml, 250 ml, 500 ml, 1000 ml plastic container.
100 ml, 250 ml, 500 ml or 1000 ml PVC bag.

Method of administration
In the special case of rapid infusion under external pressure which may be necessary in emergency situations, before starting the infusion, all air must be removed from containers with air space inside, as otherwise there is a risk of producing air embolism during the infusion.

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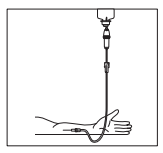
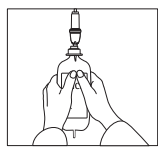
Australia (Fiji)+(Pisle); Malaysia
Font size 8
Production site Penang

Instructions for Handling the Ecoflac plus Container

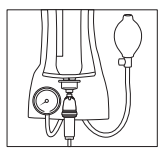
1. Gravity infusion
- Insert infusion set, fill half of drip chamber, fill infusion tube avoiding bubbles.
- Close air vent of infusion set.
- Connect infusion tube to cannula/catheter.
- Open clamp and start infusion with air vent closed



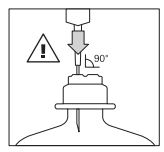
2. Pressure infusion
- Insert infusion set.
- Hold container upright.
- Leave clamp open, expel air from container and fill half of drip chamber.
- Turn container and expel air from infusion device.
- Close clamp.



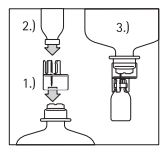
- Place container in pressure cuff.
- Build up pressure.
- Open clamp and start infusion.



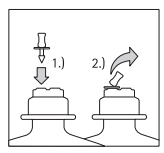
3. Admixture of additives
Addition via cannula
- Insert cannula vertically.



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.

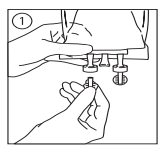


Documentation of addition and re-sealing the injection port with Ecopin®
1.) Insert Ecopin® into injection port
2.) Break off handle

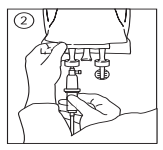


Instructions for Handling the Ecobag Container

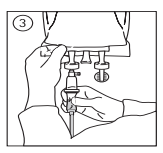
1. Preparation of the container
- Check container and closure are intact.
- Check contents for clarity and discoloration
- Open container by twisting off the corresponding toggle. The opened infusion port site is sterile. (⇨ Infusion port)



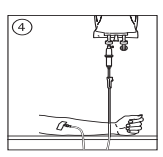
2. Gravity infusion
- Close air vent and roller clamp of infusion set.
- Insert infusion set.



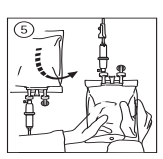
3. Gravity infusion
- Fill half of drip chamber.
- Fill infusion tube avoiding bubbles.



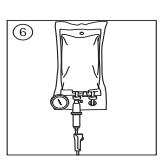
4. Gravity infusion
- Connect infusion tube to cannula/catheter.
- Start infusion, leaving air vent closed.



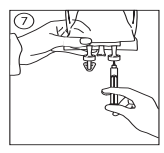
5. Pressure infusion
- Insert infusion set.
- Hold container upright.
- Leave roller clamp open, expel air from container and fill half of drip chamber.
- Turn container and expel air from infusion set.
- Close roller clamp.



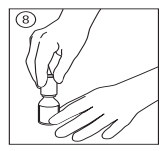
6. Pressure infusion
- Place container in pressure cuff.
- Build up pressure.
- Open roller clamp and start infusion.



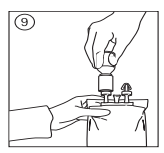
7. Admixture of additives with syringe
- Open the additive port by twisting off the corresponding toggle. The opened port site is sterile.
- Inject additive



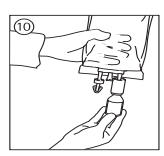
8. Admixture of additives with transfer set
- Open medication vial and disinfect injection site of the vial.
- Attach transfer set to the vial and insert until it fits firmly.
- In the case of evacuated vials first attach transfer set to the bag.



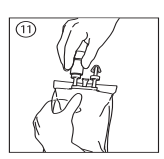
9. Admixture of additives with transfer set
- Open the additive port by twisting off the corresponding toggle. The opened port site is sterile.
- Attach transfer set together with the vial to the additive port and insert until it fits firmly.



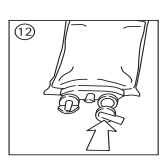
10. Admixture of additives with transfer set
- Transfer fluid into the vial by repeated pressing of the bag.
- Dissolve contents completely.



11. Admixture of additives with transfer set
- Turn bag with attached vial upside down.
- Transfer solution with dissolved additive from the vial to the bag by pressing air into the vial.
- After transfer is complete, remove vial and transfer set from the bag



12. Admixture
- Cover injection port reversibly with the Memory Cap (i.e. the twisted off toggle).



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