Directions for use

B. Braun 0.9% Sodium Chloride Intravenous Infusion B.P.

1 NAME OF THE MEDICINAL PRODUCT

B. Braun 0.9% Sodium Chloride Intravenous Infusion B.P.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contain

Sodium chloride	9.00 g
Electrolyte concentrations:	
Sodium	154 mmol/l
Chloride	154 mmol/l

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for infusion
Product description: A clear and colourless solution

Theoretical osmolarity	308 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults

The dose is adjusted according to the actual requirements of water and electrolytes.

Maximum daily dose:

Up to 40 ml per kg body weight per day, corresponding to 6 mmol of sodium per kg body weight.

Any additional losses (due to e.g. fever, diarrhoea, vomiting, etc.) should be substituted according to the volume and composition of the lost fluids.

In the management of acute volume deficiency, i.e. imminent or manifest hypovolaemic shock, higher doses may be applied, e.g. by pressure infusion.

General recommendation for treatment of sodium deficiency:

The amount of sodium required for restoration of plasma sodium level can be calculated by the equation:

Sodium requirement [mmol] = (desired – actual serum Na) × TBW

where TBW (total body water) is calculated as a fraction of body weight. The fraction is 0.6 in children, 0.6 and 0.5 in non-elderly males and females and 0.5 and 0.45 in elderly males and females, respectively.

Infusion rate:

The infusion rate will depend on the conditions of the individual patient (see section 4.4).

Elderly population

Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

Paediatric population

The dose has to be adjusted according to the individual need of water and electrolytes as well as the patient`s age, weight and clinical condition.

In case of severe dehydration a bolus of 20 ml/kg body weight is recommended for the first hour of treatment.

When administering this solution the total daily fluid intake should be taken into account.

Vehicle solution

When Sodium Chloride 9 mg/ml is used as vehicle solution, the dosage and the infusion rate will be principally guided by the nature and the dosage regimen of the additive.

Wound irrigation

The amount of solution to be used for wound irrigation or moistening depends on actual requirements.

Route of administration I.V.

Method of administration

Intravenous use

When performing pressure infusion, using solution packed in a flexible container, all air must be expelled from the container and the giving set prior to starting the infusion.

4.3 Contraindications

0.9% Sodium Chloride Intravenous Infusion must not be administered to patients in states of

- hyperhydration
- severe hypernatraemia
- severe hyperchloraemia

4.4 Special warnings and precautions for use

B. Braun 0.9% Sodium Chloride Intravenous Infusion B.P. 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.

To prevent development of the osmotic demyelination syndrome the increase of the serum sodium level should not exceed 9 mmol/l/day. As a general recommendation a correction rate of 4 to 6 mmol/l/day is reasonable in most cases, depending on patient condition and concomitant risk factors.

Clinical monitoring should include checks of the serum ionogram, the water balance, and the acid-base status.

Carefully monitoring of cardiovascular and respiratory status should be performed if a rapid infusion of 0.9% NaCl is necessary.

Please note: If this solution is used as vehicle solution the safety information of the additive provided by the respective manufacturer have to be taken into account.

Paediatric population

Premature or term infants may retain an excess of sodium due to immature renal function. In premature or term infants, repeated infusion of sodium chloride should therefore only be given after determination of the serum sodium level.

4.5 Interaction with other medicinal products and other forms of interaction

Medicinal products causing sodium retention

The concomitant use of sodium-retaining drugs (e.g. corticosteroids, non-steroidal anti-inflammatory agents) may lead to oedema.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is a limited amount of data from the use of 0.9% Sodium Chloride Intravenous Infusion in pregnant women. These data do not indicate direct or indirect harmful effects of 0.9% Sodium Chloride Intravenous Infusion with respect to reproductive toxicity (see section 5.3).

As the concentrations of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated.

Therefore, 0.9% Sodium Chloride Intravenous Infusion can be used as indicated.

Nevertheless, caution has to be exercised in the presence of eclampsia (see section 4.4).

Lactation

As the concentration of sodium and chloride are similar to that in human body no harmful effects are to be expected if the product is used as indicated.

0.9% Sodium Chloride Intravenous Infusion can be used during breast-feeding, if required.

Fertility

No data available

4.7 Effects on ability to drive and use machines

0.9% Sodium Chloride Intravenous Infusion has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

None known if used according to the instructions given.

4.9 Overdose

Symptoms

Overdose of 0.9% Sodium Chloride Intravenous Infusion may result in hypernatraemia, hyperchloraemia, hyper-hydration, acute volume overload, oedema, hyperosmolarity of the serum and hyperchloraemic acidosis.

Rapid increase of the serum sodium level in patients with chronic hyponatraemia may lead to the osmotic demyelination syndrome (see section 4.4).

First sign of overdose can be thirst, confusion, sweating, headache, weakness, somnolence or tachycardia. In case of severe hypernatraemia hypertension or hypotension, respiratory failure or coma can occur.

Treatment

Depending on the severity of the disorders immediate stop of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances.

In severe cases of overdose or in case of oligo- or anuria dialysis may become necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions affecting the electrolyte balance, electrolytes ATC-code: B05B B01

Mechanism of action

Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this. Sodium is one of the major mediators of bioelectric processes within the body.

Chloride is the principal osmotic active anion in the extracellular space.

An increase of the serum chloride level leads to enhanced renal excretion of bicarbonate. Thus an acidifying effect is induced by chloride administration.

Pharmacodynamic effects

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.

5.2 Pharmacokinetic properties

Absorption

As the solution is administered by intravenous infusion the bioavailability of the solution is 100%.

Distribution

The total sodium content of the body is ca. 80 mmol/kg (5600 mmol); of this 300 mmol are in the intracellular fluid in a concentration of 2 mmol/l and 2500 mmol are sequestered in bone. About 2 mol are in the ECF at a concentration of about 135-145 mmol/l (3.1-3.3 g/l).

The total body chloride in adults is about 33 mmol/kg body weight. Serum chloride is maintained at 98 – 108 mmol/l.

Biotransformation

Although sodium and chloride is absorbed, distributed, and excreted, there is no metabolism in the strict sense.

The kidneys are the major regulator of the sodium and water balances. In co-operation 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.

Elimination

Sodium and chloride ions are excreted via sweat, urine and gastrointestinal tract.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

When mixing with other medicinal products, possible incompatibilities should be considered.

6.3 Shelf life

Unopened

3 years

After first opening

Not applicable, see also section 6.6.

After dilution or admixture of additives

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

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schwarz (20%, 100%)

Dokument = 210 x 594 mm
2 Seiten

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6.4 Special precautions for storage

Do not store above 30 °C.

For storage conditions after dilution of the medicinal product, see section 6.3.

6.5 Nature and contents of container

The product is supplied in polyethylene bottles, containing:
50 ml, 100 ml, 250 ml, 500 ml, 1000 ml, 50 × 50 ml, 20 x 100 ml, 30 × 250 ml, 10 × 500 ml, 10 × 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Containers are for single use only. Discard container and any unused content after use.

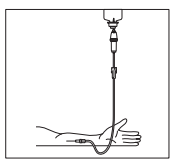
Do not use if the solution is not clear, colourless or the container or its closure show visible signs of damage.

7 DATE OF REVISION OF THE TEXT

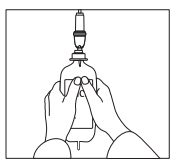
03.2023

Instructions for Handling the Ecoflac plus Container

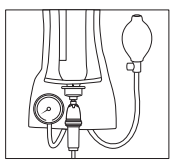
1. Gravity infusion
- Insert infusion set, fill half of drip chamber, fill infusion tube avoiding bubbles.
- Close air vent of infusion set.
- Connect infusion tube to cannula/catheter.
- Open clamp and start infusion with air vent closed



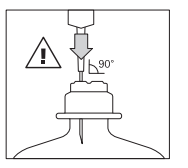
2. Pressure infusion
- Insert infusion set.
- Hold container upright.
- Leave clamp open, expel air from container and fill half of drip chamber.
- Turn container and expel air from infusion device.
- Close clamp.



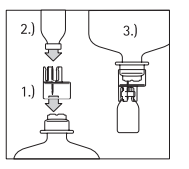
- Place container in pressure cuff.
- Build up pressure.
- Open clamp and start infusion.



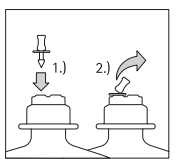
3. Admixture of additives
Addition via cannula
- Insert cannula vertically.



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



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Product Registration Holder and
Manufactured by:
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