DIRECTIONS FOR USE

6/12627822/0323

B. Braun 0.9% Sodium Chloride and 5% Glucose Intravenous Infusion B.P.

1. NAME OF THE MEDICINAL PRODUCT

B. Braun 0.9% Sodium Chloride and 5% Glucose Intravenous Infusion B.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1000 ml of solution contains

Sodium chloride	9.0 g
Glucose	50.0 g
(as glucose monohydrate, 55.0 g)	

Electrolytes

Sodium	154 mmol/l
Chloride	154 mmol/l

For the full list of excipients see section 6.1

PHARMACEUTICAL FORM

Solution for infusion;
A clear and colourless solution

Energy:	835 kJ/l ≙ 200 kcal/l
Theoretical osmolarity:	586 mOsm/l

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Dehydration
- Sodium and chloride depletion
- Caloric supply
- Vehicle solution for supplementary medication

4.2 Posology and method of administration

Approximately 1000 ml/day
Drop rate: 120 - 180 drops/min corresponding to 360 - 540 ml/h

Method of administration

Intravenous use
Hypertonic solutions should be administered in a large peripheral or central vein to diminish the risk of causing irritation.
Route of administration I.V.

4.3 Contraindications

0.9% Sodium Chloride and 5% Glucose Intravenous Infusion must not be used in cases of

- hyperhydration
- hypertonic dehydration
- lactic acidosis
- persistent hyperglycaemia not responding to insulin doses of up to 6 units/hour
- pulmonary or brain oedema
- severe hypernatraemia
- severe hyperchloraemia
- acute congestive heart failure

4.4 Special warnings and precautions for use

0.9% Sodium Chloride and 5% Glucose Intravenous Infusion should only be administered with caution in cases of

- hypernatraemia
- hyperchloraemia
- disorders where restriction of fluid or sodium intake are indicated, such as cardiac insufficiency, generalized oedema, hypertension, pre-eclampsia, severe renal insufficiency
- In patients with acute ischaemic stroke and hyperglycaemia the glucose level should be corrected before application of this solution
- Hypokalaemia

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.

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

Clinical monitoring should include checks of the serum electrolytes (especially potassium), glucose level, the acid-base and water balance.

In post-operative and post-traumatic conditions and in conditions of impaired glucose tolerance: only administer with monitoring of blood glucose level.

The solution should not be administered through the same infusion equipment simultaneously, before or after an administration of blood because of the possibility of pseudo-agglutination.

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.

In addition, intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. Adequate hydration and urine flow must be ensured and fluid balance, plasma and urinary electrolyte concentrations should be closely monitored.

4.5 Interactions with other medicinal products and other forms of interaction

Medicinal products causing sodium retention
The concomitant use of sodium-retaining drugs (e.g. corti-costeroids, non-steroidal anti-inflammatory agents) may lead to oedema.

Medicinal products influencing the glucose metabolism
Interactions with medicinal products influencing the glucose metabolism e.g. corticosteroids should be considered.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of 0.9% Sodium Chloride and 5% Glucose Intravenous Infusion in pregnant women. Animal studies relating to glucose and sodium chloride do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development (see section 5.3).
Caution should be exercised when prescribing to pregnant women, especially in the presence of pre-eclampsia (see section 4.4).
Careful monitoring of blood glucose is necessary.

Breast-feeding
As all active ingredients are present in human body, no negative effects are anticipated if used during lactation. Therefore, the solution can be used during breast-feeding.

Fertility
No data available.

4.7 Effects on ability to drive and use machines

0.9% Sodium Chloride and 5% Glucose Intravenous Infusion has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are listed according to their frequencies as follows:

Very common	(≥ 1/10)
Common	(≥ 1/100 to < 1/10)
Uncommon	(≥ 1/1,000 to < 1/100)
Rare	(≥ 1/10,000 to < 1/1,000)
Very rare	(< 1/10,000)
Not known	(cannot be estimated from the available data)

General disorders and administration site conditions:

Not known: Local reactions at infusion site, including local pain and venous irritation.

4.9 Overdose

Symptoms
Overdose of 0.9% Sodium Chloride and 5% Glucose Intravenous Infusion may result in hyperhydration, with increased skin tension, venous congestion and development of oedema. Dilution of serum electrolytes,electrolyte imbalances, notably hypernatraemia, hyperchloraemia (see section 4.8) and hypokalae-mia, acid-base imbalances may occur. In addition, hyperglycaemia, glucosuria and hyperosmolar dehydration and, in extreme cases, hyperglycaemic-hyperosmolar coma may occur.

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Treatment
Dependent 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, administration of insulin if necessary.

In severe cases of overdose or in cases of oligo or anuria dialysis may be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group

Solutions affecting the electrolyte balance
ATC code: B05B B02 (Electrolytes with carbohydrates)

Mechanism of action
The solution contains equimolar proportions of sodium and chloride corresponding to the physiological concentration in the plasma. In addition this solution also contains 5 % (w/v) of carbohydrate in the form of glucose.

Sodium is the primary cation of the extracellular space and together with various anions, regulates the size of this space. 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 results in a reduction of the body's free water content independent of the serum osmolality.

Glucose is metabolized ubiquitously as the natural substrate of the cells of the body. Under physiological conditions glucose is the most important energy-supplying carbohydrate with a caloric value of ca. 16 kJ or 3.75 kcal/g. nervous tissue, erythrocytes and medulla of the kidneys are amongst the tissues with an obligate requirement for glucose. In adults, the concentration of glucose in the blood is 70 – 100 mg/100 ml, or 3.9 – 5.6 mmol/l (fasting).

One the one hand, glucose serves for the synthesis of glycogen as the storage form of carbohydrates and, on the other hand, it is subject to glycolysis to pyruvate and lactate for energy production in the cells. Glucose also serves to maintain the blood sugar level and for the synthesis of important body components. It is primarily insulin, glucagon, glucocorticoids and catecholamines that are involved in the regulation of the blood sugar concentration.

A normal electrolyte and acid-base status is a prerequisite for the optimal utilization of administered glucose. So an acidosis, in particular, can indicate impairment of the oxidative glucose metabolism.

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 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).

On infusion glucose is first distributed in the intravascular space and then is taken up into the intracellular space.

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

Biotransformation
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.

In glycolysis glucose is metabolized to pyruvate or to lactate. Lactate can be partially re-introduced into the glucose metabolism (Cori cycle). Under aerobic conditions pyruvate is completely oxidized to carbon dioxide and water.

Glucose utilisation disturbances (glucose intolerance) can occur under conditions of pathological metabolism. These mainly include diabetes mellitus and states of metabolic stress (e.g. intra-, and postoperatively, severe disease, injury), hormonally mediated depression of glucose tolerance, which can even lead to hyperglycaemia without exogenous supply of the substrate. Hyperglycaemia can - depending on its severity - lead to osmotically mediated renal fluid losses with consecutive hypertonic dehydration, to hyperosmotic disorders up to and including hyperosmotic coma.

Metabolism of glucose and electrolytes are closely related to each other. Insulin facilitates potassium influx into cells. Phosphate and magnesium are involved in the enzymatic reactions associated with glucose utilization. Potassium, phosphate and magnesium requirements may therefore increase following glucose administration and may therefore have to be monitored and supplemented according to individual needs. Especially cardiac and neurological functions may be impaired without supplementation.

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

Chloride is exchanged for hydrogen carbonate in the tubule system and is, thus, involved in the regulation of the acid base balance.
The final products of the complete oxidation of glucose are eliminated via the lungs (carbon dioxide) and the kidneys (water). Practically no glucose is excreted renally by healthy persons. In pathological metabolic conditions (e.g. diabetes mellitus, postaggression metabolism) associated with hyperglycaemia (blood glucose concentrations of more than 120 mg/100 ml or 6.7 mmol/l), glucose is also excreted via the kidneys (glucosuria) when the maximum tubular resorption capacity (180 mg/100 ml or 10 mmol/l) is exceeded.

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. It should be remembered that the solution has an acidic pH, which can cause precipitation in the mixture.

6.3 Shelf life

Unopened
Polyethylene bottle: 3 years

After first opening the container:
Not applicable. See also section 6.6.

After dilution or addition 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.

6.4 Special precautions for storage

Do not store above 30°C.

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

6.5 Nature and contents of container

Polyethylene bottles, contents: 500 ml, 1000 ml
available in packs of
10 x 500 ml
10 x 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

The containers are for single use only. After use - discard container and any remaining contents. Do not reconnect partially used containers.

Only to be used if the solution is clear and colourless and the container and its closure are undamaged.

7. DATE OF REVISION OF THE TEXT

December 2022

Product Registration Holder and
Manufactured by:
B. Braun Medical Industries Sdn. Bhd.
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