

Directions for Use

B. Braun 0.18% Sodium Chloride And 4.3% Glucose Intravenous Infusion B.P.

Composition

1000 ml of the solution for infusion contain:

Sodium chloride	1.8 g
Glucose monohydrate	47.30 g
equivalent to anhydrous glucose	43.00 g

Electrolyte concentrations:

Sodium	31 mmol/l
Chloride	31 mmol/l

Excipients

Water for injections

Pharmaceutical form

Solution for infusion.

Product Description

A clear, colourless up to faintly straw-coloured aqueous solution.

Energy	720 kJ/l \triangle 172 kcal/l
Theoretical osmolality:	300 mOsm/l
Acidity (titration to pH 7.4):	< 0.5 mmol/l
pH:	3.5 – 5.5

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 one fifth of the physiological concentration in the plasma. In addition the solution also contains 4.3 % (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. Sodium and potassium are the major mediators of bioelectric processes within the body.

The solution is mainly intended to supply free water in cases of dehydration.

Pharmacodynamic effect

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.

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. 17 kJ or 4 kcal/g. Nervous tissue, erythrocytes and medulla of the kidneys are amongst the tissues with an obligate requirement for glucose.

On 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 glucose 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 glucose 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.

There are close metabolic relationships between the electrolytes and carbohydrate metabolism; potassium, in particular, is affected. The utilization of glucose is associated with an increased potassium requirement. Not taking this relationship into account can lead to considerable disturbances of potassium metabolism, which can, amongst other things, lead to massive cardiac arrhythmia.

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 approx. 80 mmol per kg body weight, of which approx. 95 % is extracellular.

In adults, the concentration of glucose in the blood is 60 – 100 mg/100 ml, or 3.3 – 5.6 mmol/l (fasting).

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

Biotransformation

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

Elimination

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.

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 associated with hyperglycaemia (e.g. diabetes mellitus, postaggression metabolism), glucose is also excreted via the kidneys (glucosuria) when (at blood glucose levels higher than 160-180 mg/100 ml or 8.8-9.9 mmol/l) the maximum tubular resorption capacity is exceeded.

Indications

- Hypertonic dehydration
- Partial coverage of energy requirements
- Vehicle solution for compatible electrolyte concentrates and medicinal products

Paediatric population

This product should only be used in paediatric specialist settings (such as renal, hepatic and cardiac units, high dependency units and intensive care units) for intravenous fluid therapy requiring the use of B. Braun 0.18% sodium chloride and 4.3% glucose to maintain fluid and electrolyte balance.

Dosage

Adults, the Elderly and Children

The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, concomitant therapy and should be determined by the consulting physician.

General guidelines

Daily dose:

Up to 40 ml/kg body weight per day, corresponding to approx. 1.7 g glucose/kg body weight per day.

Infusion and drop rate:

Up to 5 ml/kg body weight per hour, corresponding to approx. 0.2 g glucose/kg body weight per hour.

The prescribing doctor may determine individual adaptation of the dose and infusion rate, especially for children.

Monitoring

Adequate urine flow must be ensured and careful monitoring of serum electrolytes and glucose is essential.

Paediatric population

Use of B. Braun 0.18% sodium chloride and 4.3% glucose should be restricted to specialist paediatric settings such as renal, hepatic and cardiac units, high dependency units and intensive care units.

The dosage depends on the age, weight, clinical and biological (acid-base balance) conditions of the patient, concomitant therapy and should be determined by the consulting specialist.

Monitoring: Adequate urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are essential.

Elderly patients

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.

Other special patient groups

If the oxidative metabolism of glucose is impaired (e.g. in the early post-operative or posttraumatic period or in the presence of hypoxia or organ failure), the dosage should be adjusted to keep the blood glucose level close to normal values. See also section "Special warnings and precautions for use".

Approval for Printing

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B. Braun 0.18% Sodium Chloride
And 4.3% Glucose Intravenous
Infusion B.P.
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Method of administration

Intravenous infusion

This container contains a significant volume of air. To avoid risk of air embolism, this product must not be administered by pressure infusion.

Contraindications

- Hyperhydration states
- Dehydration with hyponatraemia
- Head trauma (first 24 hours)
- Persistent hyperglycaemia not responding to insulin doses of up to 6 units/hour.

Paediatric population

This product should not be used in children except in paediatric specialist settings (such as renal, hepatic and cardiac units, high dependency units and intensive care units) under expert medical supervision. See also section "Indications".

Special warnings and precautions for use

B. Braun 0.18% Sodium Chloride And 4.3% Glucose Intravenous Infusion B.P. should not be used for fluid substitution, especially rehydration therapy, without adequate electrolyte administration, because this could lead to markedly decreased serum electrolyte values, notably severe hyponatraemia, with potentially detrimental effects on the patient, e.g. brain damage or heart affections. Especially children, elderly patients and patients in poor general condition are at risk.

B. Braun 0.18% Sodium Chloride And 4.3% Glucose Intravenous Infusion B.P. shouldn't be used for routine rehydration or fluid maintenance therapy.

In patients with hyponatraemia or hypokalaemia administration of this solution must be accompanied by additional substitution of sodium or potassium as necessary to normalise the serum levels of these electrolytes.

In diabetic patients, the amount of infused glucose has to be taken into account and insulin requirements may be modified.

In patients with chronic hypernatraemia, the serum sodium concentration should not be lowered faster than at a rate of $0.5 \text{ mmol} \times \text{l}^{-1} \times \text{h}^{-1}$.

Administration of glucose solutions is not recommended after acute ischaemic strokes as hyperglycaemia was reported to worsen ischaemic brain damage and impair recovery.

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

If the oxidative metabolism of glucose is impaired close monitoring of blood glucose levels is recommended in order to prevent hyperglycaemia. See also section "Dosage".

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

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

Intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. Adequate urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are essential.

The infusion of hypotonic fluids together with the non-osmotic secretion of ADH (in pain, anxiety, the post-operative state, nausea, vomiting, pyrexia, sepsis, reduced circulating volume, respiratory disorders, CNS infections, and metabolic and endocrine disorders) may result in hyponatraemia. Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Interaction with other medicinal products and other forms of interaction

Corticosteroids are associated with the retention of sodium and water.

Pregnancy and lactation

Pregnancy

There is a limited amount of data from the use of sodium chloride and glucose in pregnant women. Animal studies relating to physiological amounts of glucose and sodium chloride do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition or postnatal development.

Caution should be exercised when prescribing to pregnant women especially in the presence of (pre-) eclampsia.

Careful monitoring of blood glucose is necessary.

Breast-feeding

It is known that glucose/metabolites are excreted in human milk, but at therapeutic doses of B. Braun 0.18% Sodium Chloride And 4.3% Glucose Intravenous Infusion B.P. no effects on the breastfed newborns/infants are anticipated.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

Metabolism and nutrition disorders:

Severe hyponatraemia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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.

Overdose

Symptoms

Overdose may result in hyperhydration, electrolyte imbalances (especially hypokalaemia and hyponatraemia) acid-base imbalances, and hyperglycaemia. Severe hyponatraemia could lead to death.

Clinical symptoms of water intoxication may also occur, such as nausea, vomiting, spasms.

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, administration of insulin if necessary.

In severe cases of overdose dialysis may be necessary.

Incompatibilities

When mixing with other medicinal products possible incompatibilities should be considered. It should be remembered that the solution has an acid pH, which can cause precipitation in the mixture.

Shelf life

The product must not be used beyond the expiry date stated on the labelling.

After first opening the container

Containers once opened must be used immediately and must not stored for later use. See also section "Special precautions for disposal".

After dilution

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 and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for storage

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

For storage conditions after dilution of the medicinal product, see section "Shelf life".

Presentation

500 ml, 1000 ml

Not all pack sizes may be marketed.

Special precautions for disposal

No special requirements for disposal.

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

Do not re-connect partially used containers.

Only to be used if solution is clear, colourless up to faintly straw-coloured and the container and its closure are undamaged.

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Product registration holder and manufactured by:
B. Braun Medical Industries Sdn. Bhd.
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