SUMMARY OF PRODUCT CHARACTERISTICS

ANHYDROUS GLUCOSE 5% w/v AND SODIUM CHLORIDE 0.9% w/v INTRAVENOUS INFUSION (DNS)

About medicine

Prescription only medicine

1. Name of the medicinal product

Sodium Chloride 0.9% w/v and anhydrous Glucose 5.0% w/v Intravenous Infusion B.P (DNS)

2. Qualitative and quantitative composition

Each 1000ml contains

Sodium Chloride	9.0 g
Glucose anhydrous	50.0 g

Electrolytes

Sodium	154 mmol/L
Chloride	154 mmol/L

For the full list of excipients: see section 6.1

3. Pharmaceutical form

Solution for infusion.

A clear colourless or faintly straw-coloured solution which contains 0.9%w/v sodium chloride and 5.0% glucose anhydrous dissolved in water for injections.

4. Clinical particulars

4.1 Therapeutic indications

• Fluid and electrolyte substitution in hypochloraemic alkalosis

• Chloride losses

• Hypotonic dehydration

• Isotonic dehydration

• Partial coverage of energy requirements

• Vehicle solution for compatible electrolyte concentrates and medicaments

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4.2 Posology and method of administration

Posology

Adults

The dose is adjusted according to the individual requirements of fluid, electrolyte and energy. thus the patient`s age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.

Maximum daily dose:

40 ml/kg body weight (BW) per day, corresponding to 2 g glucose/kg BW per day and 6 mmol of sodium /kg BW per day

Maximum infusion rate:

5 ml/kg BW per hour, corresponding to 0.25 g glucose/kg BW per hour.

Partial coverage of energy requirements, i. e. substitution of the obligatory daily glucose requirements, is only possible with the maximum dose stated above.

Peadiatric patients

The dose is adjusted according to the individual requirements of fluid, electrolytes and energy. Thus the patients age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.

When administering this solution the total daily fluid and glucose requirements should be taken into account.

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 post-traumatic 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. Close monitoring of blood glucose levels is recommended in order to prevent hyperglycaemia. See also section 4.4.

Method of administration

Intravenous use

Hypertonic solutions should be administered in a large peripheral or central vein to diminish the risk of causing irritaion.

To avoid risk of air embolism, this product must not be administered by pressure infusion

4.3 Contraindications

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

• hyperhydration
• hypertonic dehydration
• untreated hypokalaemia
• metabolic acidosis
• persistent hyperglycaemia not responding to insulin doses of up to 6 units/hour
• pulmonary or brain oedema
• decompensated cardiac insufficiency

4.4 Special warnings and precautions for use

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

• hypernatraemia
• hyperchloraemia
• disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency

In patients with acute ischaemic stroke and hyperglycaemia the glucose level should be corrected before application of this solution.

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

To prevent development of the osmotic demyelination syndrome in patients with chronic hyponatraemia the rate of administration should be sufficiently low, so that the serum sodium will not increase faster than by 0.35 - 0.5 mmol/h corresponding to 8 - 12 mmol/l/d.

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.

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.

In case of an adverse reaction, infusion must be stopped immediately.

4.5 Interaction with Other Medicinal Products And Other Forms Of Interaction

Corticosteroids

Corticosteroids are associated with the retention of sodium and fluid

4.6 Fertility, Pregnancy and Lactation

Pregnancy

There is a limited amount of data from the use of this Sodium Chloride 0.9 % w/v and Glucose 5 % w/v Intravenous Infusion BP 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).

Therefore, caution should be exercised when prescribing to pregnant women, especially in the presence of eclampsia (see section 4.4).

Careful monitoring of blood glucose is necessary.

Lactation

It is unknown whether Sodium Chloride 0.9 % w/v and Glucose 5 % w/v Intravenous Infusion BP or metabolites are excreted into breast-milk. As all active ingredients are present in human body, no negative effects are anticipated if used during lactation. Therefore, the solution can be used as indicated.

Fertility

Not relevant

4.7 Effects on ability to drive and use machines

Has no influence on the ability to drive and operate an automobile or other heavy machinery.

4.8 Undesirable effects

Adverse reactions may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis.

Adverse reactions may be associated with the medications added to the solution; the nature of the additive will determine the likelihood of any other undesirable effects

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.

Suspected adverse reactions can be reported via email on drugsafety@abacuspharma.com or through telephone on **+256 786 557 530**

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4.9 Overdose

Symptoms

Overdose may result in hyperhydration, with increased skin tension, venous congestion, oedema - possibly also lung or brain oedema -, dilution of serum electrolytes,electrolyte imbalances, notably hypernatraemia, hyperchloraemia (see section 4.8) and hypokalaemia, acid-base imbalances, hyperglycaemia, and hyperosmolarity of the serum (up to hyperglycaemic-hyperosmolar coma).

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 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. Sodium and potassium are the major mediators of bioelectric processes within the body.

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Therapeutic 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.

An increase in the sodium content of the body results also means 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 60 – 100 mg/100 ml, or 3.3 – 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.

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.

Elimination

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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and toxicity to reproduction.

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Since the components of Sodium Chloride 0.9 % w/v and Glucose 5 % w/v Intravenous Infusion BP are physiologically present in human body, no harmful effects are to be expected with respect to genotoxicity and carcinogenic potential.

6. Pharmaceutical particulars

6.1 List of excipients

- Water For Injections BP.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

As a guidance the following medications are incompatible with the Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion (non-exhaustive listing):

• Ampicillin sodium

• Mitomycin

• Amphotericin B

• Erythromycin lactobionate.

Because of the presence of glucose, Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion should not be administered through the same infusion equipment as whole blood, as haemolysis and clumping can occur.

Those additives known to be incompatible should not be used.

6.3 Shelf life

36 months.

Use immediately after first opening.

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Shelf life after admixture of additives

The chemical and physical stability and compatibility of any additive at the pH of Sodium Chloride 0.9%w/v & Glucose 5% w/v Infusion in the container should be established prior to use. 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

6.4 Special precautions for storage

Do not store above 30°C and do not freeze.

6.5 Nature and contents of container

Pack sizes: 250mL, and 500 mL.

The bottles are made from Low Density Polyethylene plastic; the bottles are then overwrapped with a protective plastic pouch made of biaxially oriented polyethylene (BOPP).

6.6 Special precautions for disposal and other handling

For I.V. Injection The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

Use as directed by the physician.

Keep out of reach of children.

Do not use unless solution is clear and the container is undamaged.

Any contents of the product remaining after use should be discarded in accordance with local requirements. Do not reconnect partially used containers.

In case of an adverse reaction, infusion must be stopped immediately

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7. Marketing authorisation holder

Abacus Parenteral Drugs Limited

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P.O. Box 31376, Kampala, Uganda.

Email: apdl@abacuspharma.com

Website: www.abacusparenteral.com

8. Marketing authorisation number (s)

UGANDA: NDA/MAL/HDP/0889

KENYA: H2019/CTD4401/483ER

TANZANIA: TZ14H088

9. Date of first authorisation/renewal of the authorisation

N/A

10. Date of revision of the text

January 2024