Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Aventra 5% Dextrose Infusion

2. Qualitative and quantitative composition

Dextrose (glucose) monohydrate equivalent to 5% anhydrous dextrose (5g/100ml).

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Clear colourless solution for infusion without particles in bags, individually overwrapped.

4. Clinical particulars

4.1 Therapeutic indications

5% Dextrose infusion solution is indicated for:

- Fluid replacement administered alone or in regimens dextrose compatible electrolytes or additives.
- Medium for parenteral administration of compatible medicinal products

4.2 Posology and method of administration

Posology

Adults, older people, and children:

Fluid balance, serum glucose, serum sodium and other electrolytes may need to be monitored before and during administration, especially in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs due to the risk of hyponatraemia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. 5% Dextrose Infusion Solution may become extremely hypotonic after administration due to glucose metabolization in the body. To avoid dehydration in a healthy adult or in patients with no complicated factors such as fever or excessive fluid losses, daily fluid requirements are 1.5 to 2.5 litres. The volume of glucose solution needed to replenish deficits will vary with body weight, complementary treatment, severity of the clinical condition and hydration status of the patient, but in adults will usually lie between 500ml and 3000ml every 24 hours.

The pathophysiological response to dehydration, to electrolyte loss and to glucose infusion will vary with the age of the patient being treated and this should be considered during rehydration therapy. There is no recommended dose as this is a matter for clinical judgment and laboratory assessment in each case. The dose range is typically 500 – 3000ml in a 24-hour period and typical maximum rates are 800mg/kg/hr or 600ml/hr. For intravenous infusion under medical supervision.

Method of administration

The solution is for administration by intravenous infusion through a sterile and non pyrogenic administration set, using aseptic technique.

The equipment should be primed with the solution to prevent air entering the system. The product should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless solution is clear, free from visible particles and the seal is intact. Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the solution. Administer immediately following the insertion of infusion set. Do not connect flexible plastic containers in series to avoid air embolism due to possible residual air contained in the primary container. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers. Additives may be introduced before infusion or during infusion through the injection site.

4.3 Contraindications

Hyperglycaemia. Conditions of water excess.
Hypersensitivity to the active substance.

4.4 Special warnings and precautions for use

Fluid balance/renal function
Use in patients with (severe) renal impairment: The rate of infusion should be sufficiently slow to allow the detection of osmotic diuresis - Prior to and during infusion, serum and/or urinary electrolytes and glucose should be monitored to assess the nature and severity of fluid depletion and electrolyte imbalance. Close monitoring of patients with diabetes mellitus, and in patients with renal failure, is necessary during glucose infusion. - Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration) - Use with care in patients who have suffered an acute ischaemic stroke. - Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely physiologically hypotonic due to rapid glucose metabolization. Depending on the tonicity of the solution, the volume and rate of infusion and depending on a patient's underlying clinical condition and capability to metabolize glucose, intravenous administration of glucose can cause electrolyte disturbances most importantly hypo- or hyperosmotic hyponatremia. Hyponatremia: Patients with non-osmotic vasopressin release (e.g., in acute illness, pain, post-operative stress, infections, burns, and CNS diseases), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists are at particular risk of acute hyponatremia upon infusion of hypotonic fluids. Acute hyponatremia can lead to acute hyponatremic encephalopathy (brain oedema) characterized by headache, nausea, seizures, lethargy, and vomiting. Patients with brain oedema are at particular risk of severe, irreversible,

and life-threatening brain injury. Children, women in the fertile age, and patients with reduced cerebral compliance (e.g., meningitis, intracranial bleeding, and cerebral contusion) are at particular risk of severe and life-threatening brain swelling caused by acute hyponatremia.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs leading to an increased vasopressin effect

The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and may increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids.

• Drugs stimulating vasopressin release include: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4 methylenedioxy-N- methamphetamine, ifosfamide, antipsychotics, narcotics.

• Drugs potentiating vasopressin action include: Chlorpropamide, NSAIDs, cyclophosphamide.

• Vasopressin analogues include Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatremia also include diuretics in general and antiepileptics such as oxcarbazepine.

4.6 Pregnancy and Lactation

It is particularly important to avoid maternal hyperglycaemia during intravenous glucose infusion in the perinatal period in view of the possibility of inducing neonatal hypoglycaemia. 5% Dextrose Infusion Solution should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatremia.

Fertility

There are no adequate data of the effect of Glucose 5% on fertility. However, no effect on fertility is expected.

Lactation

There are no adequate data of using Glucose solution during lactation. However, no effect on lactation is expected. Glucose 5% can be used during lactation.

4.7 Effects on ability to drive and use machines

No studies have been conducted on the influence of Dextrose 0.5% on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The following adverse reactions have been reported in post-marketing experience. The frequency of the adverse drug reactions listed in this section cannot be estimated from the available data.

System Organ Class	*Adverse reaction (MedDRA term)*	*Frequency*
Immune system disorders	Anaphylactic reaction* Hypersensitivity*	Not known
Metabolism and nutrition disorders	Electrolyte imbalance Hypokalaemia Hypomagnesaemia Hypophosphatemia Hyperglycaemia Dehydration Hypervolaemia Hospital acquired hyponatraemia**	Not known
Nervous system disorders	Hyponatraemic encephalopathy**	Not known
Skin and subcutaneous tissue disorders	Rash	Not known
Vascular disorders	Venous thrombosis Phlebitis	Not known
Renal and urinary disorders	Polyuria	Not known
General disorders and administration site conditions	Chills* Pyrexia* Infusion site infection Infusion site irritation for example erythema Extravasation Local reaction Pain localised	Not known

*Hospital acquired hyponatremia may cause irreversible brain injury and death, due to development of acute hyponatremic encephalopathy, frequency unknown. The following adverse reactions have not been reported with this product but may occur: • Hypernatremia (e.g., when administered to patients with nephrogenic diabetes insipidus or high nasogastric output) • Hyperchloremic metabolic acidosis • Hyponatremia, which may be symptomatic. Hyponatremia may occur when normal free water excretion is impaired. (e.g., SIADH or postoperative). If an adverse event occurs the patient should be evaluated and appropriate counter measures be taken, if needed the infusion should be stopped. The remaining part of the solution should be kept for investigation if deemed necessary. Reporting of suspected adverse drug reaction.

Reporting of suspected adverse reactions:

Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

Administration of excessive amounts of 5% Dextrose may result in fluid overload and water intoxication. Severe over-infusion is usually limited to infusion with higher concentrations of glucose solutions, which may cause plasma hyperosmolality and osmotic diuresis. Treatment is symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: electrolyte with carbohydrate. ATC code: B05BA03 Glucose is rapidly absorbed into cells and metabolized into carbon dioxide and water with the release of energy. 5% Dextrose infusion solution allows intracellular rehydration and glucose also serves as a carbohydrate source for cellular nutrition.

5.2 Pharmacokinetic properties

Glucose is metabolized via pyruvic or lactic acid to carbon dioxide and water with the release of energy.

The pharmacokinetics of the additive will depend on the nature of the drug used.

5.3 Preclinical safety data

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

6. Pharmaceutical Particulars

6.1 List of Excipients

Water for Injections

6.2 Incompatibilities

Glucose infusions are incompatible with blood for transfusion as haemolysis or clumping can occur; do not administer through the same infusion equipment as blood or blood components for transfusion (either before, during or after their administration).

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Glucose 5% solution by checking for eventual colour change and/or eventual precipitate, insoluble complexes or crystals apparition. The Instructions for Use of the medication to be added must be consulted.

6.3 Shelf-Life

3 years.

Use immediately on removal from overwrap.

6.4 Special Precautions for storage

• Store below 30°C
• Store in the original pack.
• Keep medicine away from direct sunlight and out of the reach of children.
- If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.5 Nature and Content of container

Transparent liquid placed in a 250ml, 500ml and 1000ml LDPE Bottle.

6.6 Special precautions for disposal and other handling

- Discard after single use
- Discard any unused portion.
- Do not reconnect partially used bags.
- Do not remove the unit from overwrap until ready for use. The inner bag maintains the sterility of the product

7. Marketing Authorization Holder

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8. Marketing Authorization Number

CTD11656

9. Date of first authorization/renewal of the authorization

07/02/2025

10. Date of revision of the text

05/05/2025