SUMMARY OF PRODUCT CHARACTERISTICS

1.Name of the medicinal product

Glucose 10% w/v Intravenous Infusion, BP (D10)

2.Qualitative and quantitative composition

Glucose (as Anhydrous): 100.0 g/l

Each ml contains 100mg of glucose (as anhydrous)

For the full list of excipients: see section 6.1

3.Pharmaceutical form

Solution for infusion.

A clear, colourless solution.

pH: 3.5 – 6.5

Osmolarity of 555 mOsm/l (approx)
Calorific value: 1680 kJ/l (or 400 kcal/l) (approx.)

4.Clinical particulars

4.1 Therapeutic indications

Glucose 10%w/v Intravenous Infusion is indicated for:

- Supply of carbohydrate during parenteral nutrition.
- Prevention and treatment of moderate hypoglycaemia.
- Rehydration in case of water loss and dehydration states.
- Dilution of compatible medicinal products.

4.2 Posology and method of administration

Posology

The dosage and rate of administration of Glucose 10% w/v Solution for Infusion are determined by several factors including the indication for use and the patient's age, weight and clinical

condition.

Fluid balance, serum glucose, serum sodium and other electrolytes should 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. Glucose 10% w/v Solution for Infusion may become extremely hypotonic after administration due to glucose metabolisation in the body (see sections 4.4, 4.5 and 4.8).

Adults and elderly:

The recommended doses in Table 1 serve as a guideline for an average adult with a body weight of approximately 70 kg.

Table 1.
Guidance on the Dose for Administration to an Adult (70kg)(*)

Indication	Initial daily dose	Rate of administration	Recommended duration of treatment
Supply of Carbohydrate alone or, as required, during parenteral nutrition	From 500 ml to 3000 ml/day (from 7 to 40 ml/kg/day)	The recommended maximum administration rate should not exceed the patient's glucose oxidation, as this may cause hyperglycaemia: 5 mg/kg/min (3 ml/kg/h)	No limit on duration - dependent on the clinical condition of the patient
Prevention and treatment of hypoglycaemia			
Rehydration in case of water loss and dehydration states in patients with high carbohydrate need			

Dilution of compatible medicinal products	From 50 to 250 ml per dose	Dependent on the nature of the additive	Dependent on the nature of the additive

*The largest volumes within recommended dose should be administered in 24 hours to avoid haemodilution.

Paediatric population:

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by a physician experienced in paediatric intravenous fluid therapy.

The recommended doses in Table 2 serve as a guideline for the paediatric population, as a function of body weight and age.

Table 2.

Guidance on the Dose for Administration to Paediatric Population

* The infusion rate, volume and duration of therapy depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy and should be determined by a physician experienced in paediatric intravenous fluid therapy.

Indication		Initial Rate of Administration*

	Initial daily dose	Preterm and term newborn infants	Infants and toddlers (1-23 months)	Children (2-11 years)	Adolescents (12 to 16-18 years)
Supply of carbohydrate alone, or, as	• **0-10 kg body weight (BW)** 100 ml/kg/day	6-11 ml/kg/h	5-11 ml/kg/h	4-8 ml/kg/h	4 ml/kg/h (7-8.5

required, during parenteral nutrition Prevention and treatment of hypoglycaemia Rehydration in case of water loss and dehydration states in patients with high carbohydrate need	• **10-20 kg body weight (BW)** 1000 ml + add 50 ml for each kg BW >10 kg/day • **> 20 kg body weight (BW)** 1500 ml + add 20 ml for each kg BW >20 kg/day	(10-18 mg/kg/min)	(9-18 mg/kg/min)	(7-14 mg/kg/min)	mg/kg/min)
Dilution of compatible medicinal products	**Initial Dose**: 50 to 100ml per dose. Not age dependent. **Rate of Administration**: Dependant on the nature of the additive. Not age dependent.				

NOTE: The largest volumes within recommended dose should be administered in 24 hours to avoid hemodilution. The maximum rate of administration should not exceed the patient's rate of glucose oxidation, as this may cause hyperglycaemia.

Depending on the patient's clinical condition, a lower flow rate than recommended can be used in order to decrease the risk of undesirable osmotic diuresis.

When the solution is used for dilution or delivery of compatible therapeutic additives for administration intravenously, the directions for use of the additive therapeutic substances will dictate the appropriate volumes for each therapy.

Method of administration:

Administration is usually via a peripheral or central vein. Glucose 10% w/v Solution for Infusion is a hypertonic solution.

The osmolarity of a final admixed infusion solution must be taken into account when peripheral administration is considered. Please see section 3 for the information about the osmolarity of the solution.

A gradual increase of flow rate should be considered when starting administration of glucose-containing products.

Precautions to be taken before handling or administering the medicinal product

The solution for infusion should be visually inspected before use.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.

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.

Electrolyte supplementation may be indicated according to the clinical needs of the patient.

Additives may be introduced before infusion or during infusion through the appropriate port. When making additions, the final osmolarity of the mixture must be measured before administration. Administration of hyperosmolar solutions may cause venous irritation and phlebitis. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored. The mixture obtained must be administered through a central or peripheral venous line depending on its final osmolarity.

Monitoring:

Treatment should be carried out under regular and careful surveillance. Clinical and biological parameters, in particular plasma-glucose concentration, fluid balance and plasma electrolytes, should be monitored on regular basis and during treatment.

4.3 Contraindications

The solution is contra-indicated in patients presenting with:

- Uncompensated diabetes and diabetes insipidus,
- Hyperosmolar coma,
- Hemodilution and extracellular hyperhydration or hypervolemia,
- Hyperglycaemia and hyperlactatemia,
- Severe renal insufficiency (with oliguria / anuria),
- Uncompensated cardiac failure,
- General oedema (including pulmonary and brain oedema) and ascitic cirrhosis,

- Other known glucose intolerances (such as metabolic stress situations).
- Hypersensitivity to the active substance.

The contra-indications related to any medicinal product that is added to the glucose solution should be considered.

4.4 Special warnings and precautions for use

Dilution and other effects on serum electrolytes

Depending on 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:

- Hyperosmolality, osmotic diuresis and dehydration
- Hypoosmolality
- Electrolyte disturbances such as
  - hyponatremia
  - hypokalaemia,
  - hypophosphatemia,
  - hypomagnesaemia,
  - overhydration/hypervolemia and, for example, congested states, including pulmonary congestion and oedema.

The above effects do not only result from the administration of electrolyte-free fluid but also from glucose administration.

Hyponatremia can develop into acute hyponatremic encephalopathy characterized by headache, nausea, seizures, lethargy, coma, cerebral oedema, and death.

Children, the elderly, women, postoperative patients, patients with hypoxia and patients with central nervous system disease or psychogenic polydipsia are at particular risk for this complication.
Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation.
Particular caution is advised in patients at increased risk of water and electrolyte disturbances that could be aggravated by increased free water load, hyperglycaemia or possibly required insulin administration.

In case of prolonged administration or high glucose dose, care should be taken to avoid hypokalaemia by monitoring plasma potassium levels and administering a potassium supplement as appropriate.
Special clinical monitoring is required at the beginning of any intravenous infusion.

Hyperglycaemia

- Rapid administration of glucose solutions may produce substantial hyperglycaemia and a hyperosmolar syndrome.
- To reduce the risk of hyperglycaemia-associated complications, the infusion rate must be adjusted and/or insulin administered
- Intravenous glucose should be administered with caution in patients with, for example:

  - impaired glucose tolerance (such as in patients with renal failure or diabetes mellitus or in the presence of sepsis, trauma, or shock)
  - severe malnutrition (risk of precipitating a refeeding syndrome),
  - thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic

acidosis due to impaired oxidative metabolization of pyruvate),

- patients with ischemic stroke or severe traumatic brain injury

Avoid infusion within the first 24 hours following head trauma. Monitor blood glucose closely as early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury.

- newborns

Effects on Insulin Secretion

Prolonged intravenous administration of glucose and associated hyperglycaemia may result in decreased rates of glucose-stimulated insulin secretion.

Hypersensitivity Reactions

- Hypersensitivity/infusion reactions, including anaphylactic/anaphylactoid reactions, have been reported with Glucose solution. Solutions containing glucose should therefore be used with caution, if at all, in patients with known allergy to corn or corn products.
- The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Refeeding syndrome

• Refeeding severely undernourished patients may result in the refeeding syndrome that is characterized by the shift of potassium, phosphorus, and magnesium intracellularly as the patient becomes anabolic. Thiamine deficiency and fluid retention may also develop. Careful monitoring and slowly increasing nutrient intakes while avoiding overfeeding can prevent these complications.

Paediatric population:

The infusion rate and volume depends on the age, weight, clinical and metabolic conditions of the patient, concomitant therapy, and should be determined by a consulting physician experienced in paediatric intravenous fluid therapy.
In order to avoid potentially fatal over infusion of intravenous fluids to the neonate, special attention needs to be paid to the method of administration. When using a syringe pump to administer intravenous fluids or medicines to neonates, a bag of fluid should not be left connected to the syringe.
When using an infusion pump all clamps on the intravenous administration set must be closed before removing the administration set from the pump, or switching the pump off. This is required regardless of whether the administration set has an anti-free flow device.
The intravenous infusion device and administration equipment must be frequently monitored.

Paediatric glycaemia related issues

Newborns – especially those born premature and with low birth weight - are at increased risk of developing hypo- or hyperglycaemia and therefore need close monitoring during treatment with intravenous glucose solutions to ensure adequate glycemic control in order to avoid potential long term adverse effects. Hypoglycaemia in the newborn can cause prolonged seizures, coma and cerebral injury. Hyperglycaemia has been associated with intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Paediatric hyponatremia-related issues

- Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatremia as well as for developing hyponatremic encephalopathy.
- Plasma electrolyte concentrations should be closely monitored in the paediatric population.
- Rapid correction of hypoosmotic hyponatremia is potentially dangerous (risk of serious neurologic complications). Dosage, rate, and duration of administration should be determined by a physician experienced in paediatric intravenous fluid therapy.

Geriatric Use

- When selecting the type of infusion solution and the volume/rate of infusion for a geriatric patient, consider that geriatric patients are generally more likely to have cardiac, renal, hepatic, and other diseases or concomitant drug therapy.

Blood

- Glucose solution (an aqueous, i.e., electrolyte-free glucose solution) should not be administered through the same equipment as whole blood, as haemolysis and pseudo- agglutination can occur.

Risk of Air Embolism

- Do not connect flexible plastic containers in series in order 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.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Both the glycaemic effects of Glucose solution and its effects on water and electrolyte balance should be taken into account when using Glucose solution in patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.
Concomitant administration of catecholamines and steroids decreases the glucose up-take.

Drugs leading to an increased vasopressin effect
The below listed drugs increase the vasopressin effect, leading to reduced renal electrolyte free water excretion and increase the risk of hospital acquired hyponatraemia following inappropriately balanced treatment with i.v. fluids (see sections 4.2, 4.4 and 4.8).

- Drugs stimulating vasopressin release, e.g.: Chlorpropamide, clofibrate, carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N- methamphetamine, ifosfamide, antipsychotics, narcotics
- Drugs potentiating vasopressin action, e.g.: Chlorpropamide, NSAIDs, cyclophosphamide
- Vasopressin analogues, e.g.: Desmopressin, oxytocin, terlipressin

Other medicinal products increasing the risk of hyponatraemia also include diuretics in general and antiepileptics such as oxcarbazepine. No interaction studies have been performed.

4.6 Fertility, Pregnancy and Lactation

When a medicinal product is added, the nature of the drug and its use during pregnancy and lactation have to be considered separately.
Intrapartum maternal intravenous glucose infusion may result in foetal insulin production, with an associated risk of foetal hyperglycaemia and metabolic acidosis as well as rebound hypoglycaemia in the neonate.

Pregnancy

Glucose solution can be used during pregnancy. However, caution should be exercised when glucose solution is used intrapartum.

Fertility

There are no adequate data of the effect of Glucose 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 solution can be used during lactation.

4.7 Effects on ability to drive and use machines

No studies have been conducted on the influence of D10 on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

The administration of Glucose 10% w/v Solution for Infusion can lead to the development of:

- Hyperglycaemia,
- Fluid-balance disturbances (hypervolaemia),
- Electrolyte disturbances (hypokalaemia, hypomagnesaemia, and hypophosphataemia). The following post-marketing adverse reactions have been reported in the post-marketing experience, listed by MedDRA System Organ Class (SOC), then, where feasible, by Preferred

Term in order of severity.

Table 3: Tabulated list of adverse reactions

System Organ Class	Adverse reaction (MedDRA term)	Frequency
Immune system disorders	Anaphylactic reaction** Hypersensitivity **	Not known (*)
Metabolism and nutrition disorders	Electrolyte disturbances Hyperglycaemia Hemodilution Hypervolaemia	
Skin and subcutaneous tissue disorders	Sweating Rash	
General disorders and administration site conditions	Chills, Shivering Pyrexia, Febrile reaction, Fever Infection at site of injection Thrombophlebitis Infusion site reactions including, • Infusion site phlebitis • Infusion site erythema	
Investigations	Glycosuria	

(*) cannot be estimated from the available data

**Potential manifestation in patients with allergy to corn,

Other adverse reactions reported with glucose injection/infusions include:

• Hyponatremia, which may be symptomatic

• Adverse reactions reported when glucose is used with parenteral nutrition:

- Hepatic failure, Hepatic cirrhosis, Hepatic fibrosis, Cholestasis, Hepatic steatosis, Blood bilirubin increased, Hepatic enzyme increased, Cholecystitis, Cholelithiasis
- Pulmonary vascular precipitates

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**

4.9 Overdose

Prolonged administration or rapid infusion of large volumes of Glucose 10% w/v Solution for Infusion may cause hyperosmolarity and hyponatraemia, dehydration, hyperglycaemia, hyperglycosuria, osmotic diuresis (due to hyperglycaemia) and water intoxication and edema. Severe hyperglycaemia and hyponatraemia may be fatal.

In case of suspected overdose, treatment with Glucose 10% must be stopped immediately. Management of overdose is symptomatic and supportive, with appropriate monitoring.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group – Solutions for Parenteral nutrition, Carbohydrates

ATC Code: B05BA03

Glucose 10% w/v Solution for Infusion is a hypertonic solution, with an approximate osmolarity of 555 mOsm/l.

The pharmacodynamic properties of this solution are those of glucose, which forms the principal source of energy in cellular metabolism. Glucose is given as a source of carbohydrate, alone or, as required, in parenteral nutrition. The Glucose 10% w/v solution provides a caloric intake of 400 kcal/l. Furthermore, glucose solution for infusion allows hydric supplementation without ionic supplementation.

When medication is added to Glucose 10% w/v Solution for Infusion, the overall pharmacodynamics of the solution will depend on the nature of the medicinal product used.

5.2 Pharmacokinetic properties

Two different pathways are involved in the metabolism of glucose: one anaerobic and one aerobic.

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

When medication is added to Glucose 10% w/v Solution for Infusion, the overall pharmacokinetics of the solution will depend on the nature of the medicinal product used.

5.3 Preclinical safety data

Preclinical safety data of this solution for infusion are not relevant since its constituents are physiological components of animal and human plasma.

The safety of potential additives should be considered separately.

6. Pharmaceutical particulars

6.1 List of excipients

Water For Injections

6.2 Incompatibilities

Glucose solution should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because haemolysis and pseudo-agglutination can occur.

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

The instructions for use of the medicinal product to be added must be consulted. Before adding a drug, verify if it is soluble and stable in water at the pH range of the Glucose 10% w/v Solution for Infusion (pH 3.5 to 6.5).

When a compatible medication is added to the Glucose Intravenous Infusion, the solution must be administered immediately.

Those additives known to be incompatible should not be used

6.3 Shelf life

Unopened 30 months

From a microbiological point of view, the diluted product must be used immediately unless dilution has taken place in controlled and validated aseptic conditions. If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Do not store above 30ºC 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 flow wrapped with a protective plastic pouch.

6.6 Special precautions for disposal and other handling

Any unused D10 or waste material should be disposed of in accordance with local requirements.

When introducing additives to D10, aseptic technique must be used.

After addition, check for a possible colour change and/or the appearance of precipitates, insoluble complexes or crystals. Mix the solution thoroughly when additives have been introduced.

Discard after single use.

Discard any unused portion.

Do not store solutions containing additives.

Do not reconnect partially used bags.

Do not remove unit from overwrap until ready for use. The inner bag maintains the sterility of the product.

Opening

a. Remove the Vial container from the overpouch just before use.

b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be compromised.

c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution

Preparation for administration

Use sterile material for preparation and administration.

d. Suspend container from eyelet support.

e. Remove plastic protector from outlet port at bottom of container:

- Grip the small wing on the neck of the port with one hand.
- Grip the large wing on the cap with the other hand and twist.
- The cap will pop off.

f. Use an aseptic method to set up the infusion.

g. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

Techniques for injection of additive medications

Warning: Additives may be incompatible. To add medication before administration

h. Disinfect medication site.

i. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture resealable medication port and inject.

j. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix. Caution: Do not store bags containing added medications.

To add medication during administration

a. Close clamp on the set.

b. Disinfect medication site.

c. Using syringe with 19 (1.10 mm) to 22 (0.70 mm) gauge needle, puncture resealable medication port and inject.

d. Remove container from IV pole and/or turn to an upright position.

e. Evacuate both ports by tapping gently while the container is in an upright position.

f. Mix solution and medication thoroughly.

g. Return container to in use position, re-open the clamp and continue administration.

7. Marketing authorisation holder

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8. Marketing authorisation number

CTD4399

9. Date of first authorisation/renewal of the authorisation

N/A

10. Date of revision of the text

January 2025