SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

UNIDEX -10 INFUSION (10% Glucose Intravenous Infusion BP)

Strength

Each 100ml contains: Glucose BP (On anhydrous basis) 10g

Pharmaceutical/Dosage form

Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml contains: Glucose BP (On anhydrous basis) 10g

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Infusion.

Clear and colorless solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Unidex -10 Infusion is indicated for:

Supply of carbohydrate alone or, as required, during parenteral nutrition.

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.

4.2 Posology and method of administration

Posology

The dosage and rate of administration of **Unidex -10 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. **Unidex -10 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	Depending on the nature of the additive	Depending 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 daily dose	Initial Rate of Administration*			
		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 required, during parenteral nutrition	• 0-10 kg body weight (BW) 100 ml/kg/day • 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	6-11 ml/kg/h (10-18 mg/kg/min)	5-11 ml/kg/h (9-18 mg/kg/min)	4-8 ml/kg/h (7-14 mg/kg/min)	4 ml/kg/h (7-8.5 mg/kg/min)
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	**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 the recommended dose should be administered in 24 hours to avoid haemodilution.

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 considered 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.

For information on incompatibility and preparation of the product and additives, please see sections 6.2 and 6.6.

Please see section 4.4 for the risk of air embolism.

4.3 Contraindications

The solution is contra-indicated in patients presenting with:

• Uncompensated diabetes and diabetes insipidus,

• Hyperosmolar coma,

• Haemodilution and extracellular hyperhydration or hypervolaemia,

• Hyperglycaemia and hyperlactataemia,

• 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. See sections 4.4 and 4.8 for corn allergies.

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

Unidex -10 Infusion are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely hypotonic due to rapid glucose metabolization (see section 4.2).

Dilution and other effects on serum electrolytes

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:

• Hyperosmolality, osmotic diuresis and dehydration

• Hypoosmolality

• Electrolyte disturbances such as

- hypo- or hyperosmotic hyponatraemia (see below),

- 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.

Hyponatraemia:

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 (see section 4.5) are at particular risk of acute hyponatraemia upon infusion of hypotonic fluids.

Acute hyponatraemia can lead to acute hyponatraemic 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 the severe and life-threatening brain swelling caused by acute hyponatraemia.

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.

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 (see below).

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 (see section 4.8). Solutions containing glucose should therefore be used with caution, if at all, in patients with known allergies to corn or corn products (see section 4.3).

• 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.

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 glycaemic 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 haemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, bronchopulmonary dysplasia, prolonged length of hospital stay, and death.

Paediatric hyponatraemia-related issues

• Children (including neonates and older children) are at increased risk of developing hypoosmotic hyponatraemia as well as for developing hyponatraemic encephalopathy.

• Plasma electrolyte concentrations should be closely monitored in the paediatric population.

• Rapid correction of hypoosmotic hyponatraemia 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 pseudoagglutination 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 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.

For methods of administration and precautions to be taken before handling or administering the medicinal product, please see also section 4.2.

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

Glucose solution should be administrated with special caution for pregnant women during labour particularly if administered in combination with oxytocin due to the risk of hyponatraemia (see section 4.4, 4.5 and 4.8).

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

None known.

4.8 Undesirable effects

The administration of **Unidex -10 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 nutritional disorders	Electrolyte disturbances Hyperglycaemia Hemodilution Hypervolaemia Hospital Acquired Hyponatraemia***	
Skin and subcutaneous tissue disorders	Sweating Rash	
Nervous system disorders	Hyponatraemic encephalopathy***	
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, see section 4.4.

*** Hospital acquired hyponatraemia may cause irreversible brain injury and death due to development of acute hyponatraemic encephalopathy (see sections 4.2 and 4.4).

Other adverse reactions reported with glucose injection/infusions include:

• 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.

4.9 Overdose
Prolonged administration or rapid infusion of large volumes of **Unidex -10 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 (see sections 4.4 and 4.8).

In case of suspected overdose, treatment with **Unidex -10 Infusion** must be stopped immediately. Management of overdose is symptomatic and supportive, with appropriate monitoring.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Unidex -10 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 **Unidex -10 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 **Unidex -10 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
Unidex -10 Infusion should not be administered simultaneously with, before or after an administration of blood through the same infusion equipment, because haemolysis and pseudoagglutination can occur.

Incompatibility of the medicinal product to be added with the solution in Viaflo container must be assessed before its addition.

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 **Unidex -10 Infusion**, the solution must be administered immediately.

Those additives known to be incompatible should not be used.

6.3 Shelf life:
3 years

6.4 Special precautions for storage
Do not store above 30°C

6.5 Nature and contents of container
LDPE (Low-density polyethylene) bottle.

Pack sizes: 500ml.

The bottle is overwrapped with nylon wrapper composed of Plain Biaxially Oriented Polypropylene (Plain BOPP). The bottles are packed into cardboard cartons containing 20 x 500ml bottles per carton.

6.6 Special precautions for disposal and other handling
- Remove the LDPE bottle from the nylon wrapper just before use.
- Check for minute leaks by squeezing inner bottle firmly. If leaks are found, discard a solution, as sterility may be impaired.
- Check the solution for clarity and absence of foreign matter. If the solution is not clear or contains foreign matter, discard the solution.

After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion.

Discard after single use. Discard any unused portion.

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

Preparation for administration

Use sterile material for preparation and administration.

- Use an aseptic method to set up the infusion.

Techniques for injection of additive medications
Warning: Some additives may be incompatible. Check additive compatibility with both the solution and container prior to use. When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.
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8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

04-0343

10. DATE OF REVISION OF THE TEXT

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