SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Unidexal– 9 Infusion (0.9% Sodium Chloride and 5% Glucose Intravenous Infusion BP)

Strength

Each 100 ml contains:

Sodium chloride BP……0.9g

Glucose BP (On anhydrous basis) ……5g

Pharmaceutical/Dosage form

Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml contains:

Sodium chloride BP……0.9g

Glucose BP (On anhydrous basis) ……5g

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Infusion.

Clear solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Unidexal-9 Infusion is indicated for the treatment of sodium depletion, extracellular dehydration or hypovolemia in cases where supply of water and carbohydrates is required due to restriction of the intake of fluids and electrolytes by normal routes.

4.2 Posology and method of administration

The choice of the specific sodium chloride and glucose concentration, dosage, volume, rate and duration of administration depends on the age, weight, clinical condition of the patient and concomitant therapy. It should be determined by a physician. For patients with electrolyte and glucose abnormalities and for pediatric patients, consult a physician experienced in intravenous fluid therapy.

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 hyponatremia. Monitoring of serum sodium is particularly important for physiologically hypotonic fluids. **Unidexal-9 Infusion** may become extremely hypotonic after administration due to glucose metabolization in the body. (see sections 4.4, 4.5 and 4.8).

Rapid correction of hyponatremia and hypernatremia is potentially dangerous (risk of serious neurologic complications). Electrolyte supplementation may be indicated according to the clinical needs of the patient

Adults, older patients and adolescents (age 12 years and over):

The recommended dosage is: 500 ml to 3 L/24h

Administration rate:

The infusion rate is usually 40 ml/kg/24h and should not exceed the patient's glucose oxidation capacities to avoid hyperglycemia. Therefore, the maximum acute administration rate is 5 mg/kg/min.

Paediatric population

The dosage varies with weight:

• 0-10 kg body weight:	100 ml / kg / 24 h
• 10-20 kg body weight:	1000 ml + (50 ml/ kg over 10 kg) / 24h
• > 20 kg body weight:	1500 ml + (20 ml/ kg over 20 kg) / 24h.

The administration rate varies with weight:

• 0-10 kg body weight:	6-8 ml/kg/h
• 10-20 kg body weight:	4-6 ml/kg/h
• > 20 kg body weight:	2-4 ml/kg/h

The infusion rate should not exceed the patient's glucose oxidation capacities in order to avoid hyperglycemia. Therefore, the maximum acute administration rate is 10-18 mg/kg/min depending on the total body mass.

For all patients, a gradual increase of flow rate should be considered when starting administration of glucose containing products.

Method of administration

The administration is performed by intravenous infusion.

Unidexal-9 Infusion is isotonic and hyperosmolar, due to the glucose content. It has an approximate osmolarity of 585 mOsmol/l.

Precautions to be taken before administering the product

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not administer unless the solution is clear, and the seal is intact. Administer immediately following the insertion of infusion set. Do not remove units from overwrap until ready for use.

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. 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 or during infusion through the resealable medication port. When Additives are used, verify tonicity prior to parenteral administration. Hyperosmolar solutions may cause venous irritation and phlebitis. Thus, any hyperosmolar solution is recommended to be administered through a large central vein, for rapid dilution of the hyperosmotic solution

For further information on the product with additives, please see sections 6.2, 6.3 and 6.6.

4.3 Contraindications

The solution is contraindicated in patients presenting with:

- Known hypersensitivity to the product
- Extracellular hyperhydration or hypervolemia
- Fluid and sodium retention
- Severe renal insufficiency (with oliguria/anuria)
- Uncompensated cardiac failure
- Hypernatraemia or hyperchloraemia
- General oedema and ascitic cirrhosis

Clinically significant hyperglycaemia. The solution is also contraindicated in case of uncompensated diabetes, other known glucose intolerances (such as metabolic stress situations), hyperosmolar coma or hyperlactataemia.

4.4 Special warnings and precautions for use

Hypokalaemia

Unidexal-9 Infusion may result in hypokalaemia. Close clinical monitoring may be warranted in patients with or at risk for hypokalaemia, for example:

• Persons with metabolic alkalosis

• Persons with thyrotoxic periodic paralysis. Administration of intravenous glucose has been associated in aggravating hypokalaemia

• Persons with increased gastrointestinal losses (e.g., diarrhea, vomiting)

• Prolonged low potassium diet

• Persons with primary hyperaldosteronism

• Patients treated with medications that increase the risk of hypokalaemia (e.g. diuretics, beta-2 agonists or insulin)

Sodium retention, fluid overload and oedema

Unidexal-9 Infusion should be used with caution in

• Patients with metabolic acidosis

• Patients at risk of

- Hypernatraemia

- Hyperchloraemia

- Hypervolaemia

• Patients with conditions that may cause sodium retention, fluid overload and oedema (central and peripheral), such as

- Primary hyperaldosteronism,

- Secondary hyperaldosteronism associated with, for example,

▪ hypertension,

• congestive heart failure,

▪ liver disease (including cirrhosis),

• renal disease (including renal artery stenosis, nephrosclerosis)

- Pre-eclampsia.

Patients taking medications that may increase the risk of sodium and fluid retention, such as corticosteroids

Hyperosmolality, serum electrolytes and water imbalance

Depending on the volume, rate of infusion, the patient's underlying clinical condition and capability to metabolize glucose, the administration of Unidexal-9 Infusion can cause:

• Hyperosmolality, osmotic diuresis and dehydration

• Electrolyte disturbances such as

- hyponatraemia (see “Sodium imbalance” below)

- hypokalaemia (see above)

- hypophosphataemia,

- hypomagnesaemia,

• Acid-base imbalance

• Overhydration/hypervolaemia and, for example, congested states, including central (e.g. pulmonary congestion) and peripheral oedema.

• An increase in serum glucose concentration is associated with an increase in serum osmolality. Osmotic diuresis associated with hyperglycaemia can result in or contribute to the development of dehydration and in electrolyte losses.

Electrolyte balance (*see 'Sodium imbalance' below)*

Glucose intravenous infusions are usually isotonic solutions. In the body, however, glucose containing fluids can become extremely hypotonic due to rapid glucose metabolization (see section 4.2).

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 hyponatraemia.

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.

Hyperglycaemia

Rapid administration of glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome. In order to avoid hyperglycaemia the infusion rate should not exceed the patient's ability to utilize glucose. To reduce the risk of hyperglycaemia-associated complications, the infusion rate must be adjusted and/or insulin administered if blood glucose levels exceed levels considered acceptable for the individual patient

Intravenous glucose should be administered with caution in patients with, for example:

• Impaired glucose tolerance (such as in diabetes mellitus, renal impairment, or in the presence of sepsis, trauma, or shock),

• Severe malnutrition (risk of precipitating a refeeding syndrome, see below),

• Thiamine deficiency, e.g., in patients with chronic alcoholism (risk of severe lactic acidosis due to impaired oxidative metabolism of pyruvate),

• Water and electrolyte disturbances that could be aggravated by increased glucose and/or free water load

Other groups of patients in whom **Unidexal-9 Infusion** should be used with caution include:

• Patients with ischemic stroke. Hyperglycaemia has been implicated in increasing cerebral ischemic brain damage and impairing recovery after acute ischemic strokes.

• Patients with severe traumatic brain injury (during the first 24 hours following the trauma). Early hyperglycaemia has been associated with poor outcomes in patients with severe traumatic brain injury.

• Newborns (See Paediatric glycaemia-related issues).

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

Hypersensitivity Reactions

• Hypersensitivity/infusion reactions, including anaphylaxis, have been reported (see section 4.8).

• Stop the infusion immediately if signs or symptoms of hypersensitivity/infusion reactions develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated.

Solutions containing glucose should be used with caution in patients with known allergies to corn or corn products

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 intake while avoiding overfeeding can prevent these complications

Severe renal impairment

Unidexal-9 Infusion should be administered with caution to patients at risk of (severe) renal impairment. In such patients, administration may result in sodium retention and/or fluid overload.

Paediatric use

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.

Paediatric glycaemia-related issues

Newborns, especially those born premature and with low birth weight, are at increased risk of developing hypo- or hyperglycaemia. Close monitoring during treatment with intravenous glucose solutions is needed to ensure adequate glycaemic control, to avoid potential long term adverse effects.

• Hypoglycaemia in the newborn can cause, e.g., prolonged seizures, coma, and cerebral injury

• Hyperglycaemia has been associated with cerebral injury, including intraventricular hemorrhage, late onset bacterial and fungal infection, retinopathy of prematurity, necrotizing enterocolitis, increased oxygen requirements, prolonged length of hospital stay, and death.

Paediatric hyponatraemia-related issues

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

• Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death; therefore, acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

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

• Rapid correction of 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

Blood

Unidexal-9 Infusion should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis.

Geriatric use

When selecting 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.

4.5 Interaction with other medicinal products and other forms of interaction

No studies have been conducted by Baxter

Both the glycaemic and effects on water and electrolyte balance should be considered when administering **Unidexal-9 Infusion** to patients treated with other substances that affect glycaemic control, or fluid and/or electrolyte balance.

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.

Caution is advised in patients treated with

• lithium. Renal sodium and lithium clearance may be increased during administration and can result in decreased lithium levels.

• corticosteroids, which are associated with the retention of sodium and water (with oedema and hypertension).

• diuretics, beta-2 agonists or insulin, who increase the risk of hypokalemia

4.6 Fertility, pregnancy and lactation

Pregnancy

Intrapartum maternal intravenous glucose infusion may result in foetal hyperglycaemia and metabolic acidosis as well as rebound neonatal hypoglycaemia due to foetal insulin production.

Fertility

There is no information on the effects of **Unidexal-9 Infusion** on fertility

Lactation

Unidexal-9 Infusion can be used during breast-feeding.

The potential risks and benefits for each specific patient should be carefully considered before administration.

4.7 Effects on ability to drive and use machines
There is no information on the effects of **Unidexal-9 Infusion** on the ability to operate an automobile or other heavy machinery.

Unidexal-9 Infusion 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).

4.8 Undesirable effects
The following adverse reactions have been reported in post-marketing experience, listed by MedDRA System Organ Class (SOC), then where feasible, by Preferred Term in order of severity.

Frequencies cannot be estimated from the available data, as all listed adverse reactions are based on spontaneous reporting.

System Organ Class	Adverse reactions (Preferred terms)	Frequency
Immune system disorders	anaphylactic reaction, * hypersensitivity*	Not known
Metabolism and nutritional disorders	hypernatraemia, hyperglycaemia, hospital acquired hyponatraemia**	Not known
Nervous system disorders	hyponatraemic encephalopathy**	Not known
Vascular disorders	phlebitis	Not known
Skin and subcutaneous tissue disorders	rash, pruritus	Not known
General disorders and administration site conditions	injection site reactions including: pyrexia chills infusion site pain infusion site vesicles	Not known

**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 isotonic saline and glucose infusions include:

• Hyponatraemia, which may be symptomatic

• Hyperchloraemic acidosis

Adverse reactions may be associated to the medicinal product(s) added to the solution; the nature of the additive will determine the likelihood of any other adverse reactions.

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
Excess administration of **Unidexal-9 Infusion** can cause:

• Hyperglycaemia, adverse effects on water and electrolyte balance and corresponding complications. For example, severe hyperglycaemia and severe dilutional hyponatraemia and their complications can be fatal.

• Hyponatraemia (which can lead to CNS manifestations, including seizures, coma, cerebral oedema and death).

• Hypernatraemia especially in patients with renal impairment.

• Fluid overload (which can lead to central and/or peripheral oedema).

• See also sections 4.4 and 4.8

A clinically significant overdose of **Unidexal-9 Infusion** may, therefore, constitute a medical emergency

When assessing an overdose, any additives in the solution must also be considered.

Interventions include discontinuation of **Unidexal-9 Infusion** administration, dose reduction, administration of insulin and other measures as indicated for the specific clinical constellation.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Unidexal-9 Infusion is an isotonic and hyperosmolar solution of sodium chloride and glucose.

The pharmacodynamic properties of this solution are those of its components (glucose, sodium and chloride).

Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na^+/K^+-ATPase). Sodium plays an important role in neurotransmission and cardiac electrophysiology, and in renal metabolism.

Chloride is mainly an extracellular anion. Intracellular chloride is high concentration in red blood cells and gastric mucosa. Reabsorption of chloride follows reabsorption of sodium.

Glucose is the principal source of energy in cellular metabolism. The glucose in this solution provides a caloric intake of 200kcal/l.

5.2 Pharmacokinetic properties
The pharmacokinetic properties of this solution are those of its components (glucose, sodium and chloride).

After injection of radiosodium (^{24}Na), the halflife is 11 to 13 days for 99% of the injected Na and one year for the remaining 1%. The distribution varies according to tissues: it is fast in muscles, liver, kidney, cartilage and skin; it is slow in erythrocytes and neurones; it is very slow in the bone. Sodium is predominantly excreted by the kidneys, but (as described earlier) there is extensive renal reabsorption. Small amounts of sodium are lost in the faeces and sweat.

The two main metabolic pathways of glucose are gluconeogenesis (energy storage) and glycogenolysis (energy release). Glucose metabolism is regulated by insulin.

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

Toxic effects are not to be expected under the condition of clinical application.

The safety of potential additives should be considered separately.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water for Injections

6.2 Incompatibilities
Incompatibility of the medicinal product to be added with the solution must be assessed before addition. In the absence of compatibility studies, this solution 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 it is soluble and stable in water at the pH of **Unidexal-9 Infusion**

(see section 3).

As guidance, the following medications are incompatible with the **Unidexal-9 Infusion**

(non-exhaustive listing):

- Ampicillin sodium

- Mitomycin

- Amphotericin B

- Erythromycin lactobionate

Those additives known to be incompatible should not be used.

Because of the presence of glucose, **Unidexal-9 Infusion** should not be administered simultaneously with blood through the same administration set because of the possibility of pseudoagglutination or haemolysis

6.3 **Shelf life:**

3 years

It is recommended that the product is used immediately once it is opened (see section 4.2).

In-use shelf life: Additives

From a physico-chemical viewpoint, solutions containing additives should be used immediately unless chemical and physical in-use stability has been established.

From a microbiological point of view, solutions containing additives 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 reconstitution has taken place in controlled and validated aseptic conditions.

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 contain 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.

Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
Tel: +234 8097421000
Email: mail@uniquepharm.com

8. DRUG PRODUCT MANUFACTURER
Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota,
Ogun State, Nigeria.
Tel: +234 8097421000
Email: mail@uniquepharm.com

9. NAFDAC REGISTRATION NUMBER(S)
04-0340

10. DATE OF REVISION OF THE TEXT
02/09/2026