SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Unidex - 50 Infusion (50% Glucose Intravenous Infusion BP)

Strength

Each 100ml contains:
Glucose BP (On anhydrous basis) 50g

Pharmaceutical/Dosage form

Infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml contains:
Glucose BP (On anhydrous basis) 50g

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 - 50 Infusion is hypertonic and provides a source of calories in a minimal volume of water. **Unidex - 50 Infusion** is frequently used in both adults and children to restore blood glucose concentrations in the treatment of hypoglycaemia resulting from insulin excess or from other causes.

Unidex - 50 Infusion may be used to provide temporary relief from the symptoms of cerebral oedema and from hypoglycaemic coma. Hyperosmotic Glucose with or without insulin may correct hyperkalaemia in renal failure.

4.2 Posology and method of administration

Fluid and acid base 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 agonists due to the risk of hyponatraemia.

Monitoring of serum sodium is particularly important for physiologically hypotonic fluids (*in vivo* tonicity). **Unidex - 50 Infusion** may become extremely hypotonic after administration due to glucose metabolism in the body (see sections 4.4, 4.5, 4.8 and 5.2).

Unidex - 50 Infusion must be administered by the intravenous route; it must not be administered by subcutaneous or intramuscular route. Except in the emergency treatment of severe hypoglycaemia, **Unidex - 50 Infusion** should be administered via a central vein after appropriate dilution. When used for the emergency treatment of hypoglycaemia, **Unidex - 50 Infusion** may be administered slowly into a peripheral vein at a rate not greater than 3mls per minute.

Dosage of Glucose depends on the age, weight, clinical condition, the fluid, electrolyte and acid base balance of the patient. For the treatment of hypoglycaemia resulting from insulin excess or other causes in adults (including the elderly) and children, the usual dose is as follows:

20-50ml of **Unidex - 50 Infusion** administered slowly intravenously. This represents 3mls per minute.

Repeated doses and supportive therapy may be required in some cases.

4.3 Contraindications

Unidex - 50 Infusion is contraindicated in patients with:

• hypersensitivity to the active substance or to any excipients listed in section 6.1 and known allergy to corn or corn products

• the glucose – galactose malabsorption syndrome

• anuria or intraspinal or intracranial haemorrhage, or ischaemic stroke and in patients with delirium tremens if such patients are already dehydrated

• with hyperglycaemic coma.

4.4 Special warnings and precautions for use

Unidex - 50 Infusion should be administered via a large central vein to minimise damage at the site of injection (see section 4.2 Posology).

Unidex - 50 Infusion should be used with caution in patients with overt or known sub-clinical diabetes mellitus, carbohydrate intolerance for any reason, severe under-nutrition, thiamine deficiency, hypophosphataemia, haemodilution, sepsis, trauma, shock, metabolic acidosis or severe dehydration.

Rapid administration of hypertonic glucose solutions may produce substantial hyperglycaemia and hyperosmolar syndrome; patients should be observed for signs of mental confusion and loss of consciousness, especially those patients with chronic uraemia or carbohydrate intolerance.

Prolonged use in parenteral nutrition may affect insulin production; blood and urine glucose should be monitored.

Unidex - 50 Infusion is a hypertonic solution (*in vitro*, in a container). In the body, however, glucose containing fluids can become extremely hypotonic due to rapid glucose metabolism (see section 4.2 and 5.2).

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 disease), patients with heart-, liver- and kidney diseases and patients exposed to vasopressin agonists (see section 4.5) are at 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.

Intravenous administration of **Unidex - 50 Infusion** may result in other electrolyte disturbances such as: hypokalaemia, hypophosphataemia and hypomagnesaemia (see sections 4.2. and 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

Drugs increasing vasopressin effect, listed below, lead 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.: carbamazepine, vincristine, selective serotonin reuptake inhibitors, 3.4-methylenedioxy-N-methamphetamine, ifosfamide, antipsychotics, narcotics

• Drugs potentiating vasopressin action, e.g.: NSAIDs, cyclophosphamide

• Vasopressin analogues, e.g.: desmopressin, oxytocin, vasopressin, terlipressin.

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

4.6 Fertility, pregnancy and lactation

Intravenous glucose may result in foetal insulin production, with an associated risk of rebound hypoglycaemia in the neonate. Infusions of glucose administered during Caesarean section and labour should not exceed 5-10g glucose/hour.

Unidex - 50 Infusion should be administered 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).

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100); Rare (≥ 1/10,000 to < 1/1,000); Very rare (<1/10,000), Not known (cannot be estimated from the available data)		
System Organ Class (SOC)	Adverse reaction (MedDRA term)	Frequency
Metabolism and nutritional disorders	Hospital acquired hyponatraemia * Hyperglycaemia** Hypokalaemia Hypophosphataemia Hypomagnesaemia Fluid and electrolyte imbalance.	Not known
Nervous system disorders	Hyponatraemic encephalopathy*	Not known
General disorders and administration site conditions	Pain at the injection site Vein irritation Venous thrombosis Phlebitis	Not known

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

** Hyperglycaemia (possibly indicated by mental confusion or loss of consciousness) and glycosuria may occur as a result of the rate of administration or metabolic insufficiency. If undetected and untreated hyperglycaemia can lead to dehydration, hyperosmolar coma and death.

The administration of glucose without adequate levels of thiamine may precipitate overt deficiency states e.g. Wernicke's encephalopathy. Sodium retention, oedema, pulmonary oedema and congestive heart failure may be induced in patients with severe under-nutrition.

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

Overdose of **Unidex - 50 Infusion** may lead to hyperglycaemia and glycosuria leading to dehydration, hyperosmolar coma and death.

In the event of an overdose of **Unidex - 50 Infusion** it may be necessary to administer appropriate doses of insulin.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solutions for parenteral nutrition, Carbohydrates

The metabolism of glucose is an energy source for the body.

5.2 Pharmacokinetic properties

Glucose is rapidly metabolised into carbon dioxide and water.

5.3 Preclinical safety data

No further information other than that which is included in the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injection BP

6.2 Incompatibilities

Glucose solutions which do not contain electrolytes should not be administered concomitantly with blood through the same infusion set, because of the possibilities of agglomeration.

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: 100ml.

The bottle is overwrapped with nylon wrapper composed of Plain Biaxially Oriented Polypropylene (Plain BOPP). The bottles are packed into cardboard cartons to contain 100 x 100ml bottles per carton.

6.6 Special precautions for disposal and other handling
Use as directed by the physician.

- 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 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.

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
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9. NAFDAC REGISTRATION NUMBER(S)

04-1483

10. DATE OF REVISION OF THE TEXT

02/07/2026